EXHIBIT 21

United States
Environmental Protection
Agency

EPA 402-F-09-002 | Revised August 2009 | www.epa.gov/iaq

RESIDENTIAL AIR CLEANERS

(Second Edition)

A SUMMARY OF AVAILABLE INFORMATION

Indoor Air Quality (IAQ)

U.S. Environmental Protection Agency
Office of Air and Radiation
Indoor Environments Division
1200 Pennsylvania Avenue, NW
Mail code: 6609J
Washington, DC 20460

www.epa.gov/iaq

Disclaimer

This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names, products, or services does not convey, and should not be interpreted as conveying official EPA approval, endorsement or recommendation.

TABLE OF CONTENTS

SUMMARY

Indoor air pollution is among the top five environmental health risks. Usually the best way to address this risk is to control or eliminate the sources of pollutants and ventilate a home with clean outdoor air. But opportunities for ventilation may be limited by weather conditions or by contaminants in the outdoor air.

If the usual methods of addressing indoor air pollution are insufficient, air-cleaning devices may be useful. Air filters and other air-cleaning devices are designed to remove pollutants from indoor air. Some are installed in the ductwork of a home's central heating, ventilating, and air-conditioning (HVAC) system to clean the air in the entire house. Portable room air cleaners can be used to clean the air in a single room or in specific areas, but they are not intended to filter the air in the whole house. Air-cleaning devices are categorized by the type of pollutants—particulate and gaseous—that the device is designed to remove or destroy.

Two types of air-cleaning devices can remove particles from the air: mechanical air filters and electronic air cleaners.

Mechanical air filters, such as high efficiency particulate air (HEPA) filters, remove particles by capturing them on filter materials. Most mechanical air filters are good at capturing larger airborne particles—such as dust, pollen, some mold spores, and animal dander—and particles that contain dust mite and cockroach allergens. But because these particles settle rather quickly, mechanical air filters are not very good at completely removing them from indoor areas.

Electronic air cleaners, such as electrostatic precipitators, use a process called electrostatic attraction to trap particles. Ion generators, or ionizers, disperse charged ions into the air. These ions attach to airborne particles, giving them a charge so they can attach to nearby surfaces such as walls or furniture, or to one another, and settle faster. However, some electronic air cleaners can produce ozone, a lung irritant.

Another type of air-cleaning device is a gas-phase filter designed to remove gases and odors by either physical or chemical processes.

Gas-phase air filters remove gaseous pollutants by using a material called a sorbent, such as activated carbon, to adsorb pollutants. Because these filters are targeted at one or a limited number of gaseous pollutants, they will not reduce concentrations of pollutants for which they were not designed. None are expected to remove all of the gaseous pollutants in the air of a typical home. Gas-phase filters are much less common in homes than are particle air filters. One reason may be the filter can become overloaded quickly and may need to be replaced often.

Three types of air cleaners on the market are designed to deactivate or destroy indoor air pollutants: ultraviolet germicidal irradiation (UVGI) cleaners, photocatalytic oxidation (PCO) cleaners, and ozone generators sold as air cleaners.

UVGI cleaners use ultraviolet radiation from UV lamps that may destroy biological pollutants such as viruses, bacteria, and molds that are airborne or growing on HVAC surfaces (e.g., cooling coils, drain pans, or ductwork). UVGI cleaners should be used with, but not as a replacement for, filtration systems. Typical UVGI cleaners used in homes have limited effectiveness in killing bacteria and molds. Effective destruction of some viruses and most mold and bacterial spores usually requires much higher UV exposures than a typical home unit provides.

PCO cleaners use UV lamps along with a substance, called a catalyst, that reacts with the light. These cleaners are designed to destroy gaseous pollutants by changing them into harmless products, but they are not designed to remove particulates. The usefulness of PCO cleaners in homes is limited because currently available catalysts are ineffective in destroying gaseous pollutants in indoor air.

Ozone generators use UV lamps or electrical discharges to produce ozone that reacts with chemical and biological pollutants and transforms them into harmless substances. Ozone is a potent lung irritant, which in concentrations that do not exceed public health standards, has little potential to remove indoor air contaminants. Thus ozone generators are not always safe and effective in controlling indoor air pollutants.

Portable air cleaners generally contain a fan to circulate the air and use one or more of the air-cleaning technologies discussed above. They may be an option if a home is not equipped with a furnace or a central air-conditioning system. Many portable air cleaners have moderate to large air delivery rates for small particles. However, most of the portable air cleaners on the market do not have high enough air delivery rates to remove large particles such as pollen and particles that contain dust mite and cockroach allergens from typical-size rooms.

Several other factors should be considered when making decisions about using air-cleaning devices.

- Installation: In-duct air-cleaning devices have certain installation requirements that must be met, including sufficient access for inspection during use, repairs, and maintenance.
- Major costs: These costs include the initial purchase price and the cost of maintenance (such as cleaning or replacing filters and parts) and operation (electricity).
- Odors: Air-cleaning devices designed to remove particles cannot control gases and some odors. The odor and many of the carcinogenic gas-phase pollutants from tobacco smoke, for example, will remain.
- Soiling of walls and other surfaces: Typical ion generators are not designed to remove from the air the charged particles that they generate. These charged particles may settle on, and soil, walls and other room surfaces.
- Noise: Noise may be a problem with portable air cleaners that contain fans. Portable air cleaners that do not have fans tend to be much less effective than units that have them.

The ability to remove some airborne pollutants, including microorganisms, is not, in itself, an indication of an air-cleaning device's ability to reduce adverse health effects from indoor pollutants. Although air-cleaning devices may help reduce levels of smaller airborne particles including those associated with allergens, they may not reduce adverse health effects, especially in sensitive populations such as children, people who have asthma and allergies, and the elderly. For example, the evidence is weak that air-cleaning devices are effective in reducing asthma symptoms associated with small airborne particles such as those that contain cat and dust mite allergens. There are no studies linking the use of gas-phase filtration, UVGI systems, or PCO systems in homes to reduced health symptoms in sensitive populations.

INTRODUCTION

The best way to address residential indoor air pollution usually is to control or eliminate the source of the pollutants and to ventilate the home with clean outdoor air. But ventilation may be limited by weather conditions or the levels of contaminants in the outdoor air.

If the usual methods of dealing with indoor air pollutants are insufficient, air-cleaning devices may be useful. Air filters and other air-cleaning devices are designed to remove pollutants from indoor air. They can be installed in the ductwork of most home heating, ventilating, and air-conditioning (HVAC) systems to clean the air in the entire house, or the same technology can be used in portable air cleaners that clean the air in single rooms or specific areas. Most air-cleaning devices are designed to remove particles or gases, but some destroy contaminants that pass through them.

This publication focuses on air cleaners for residential use; it does not address air cleaners used in large or commercial structures such as office buildings, schools, large apartment buildings, or public buildings. It should be particularly useful to residential housing design professionals, public health officials, and indoor air quality professionals. In addition to providing general information about the types of pollutants affected by air cleaners, this document discusses:

- The effectiveness of air cleaning compared to other strategies, such as source control and ventilation, for reducing indoor air pollutants.
- The types of air-cleaning devices available.
- Guidelines that can be used to compare air-cleaning devices.
- The effectiveness of air-cleaning devices in removing indoor air pollutants.
- General information on the health effects of indoor air pollutants.
- Additional factors to consider when deciding whether to use an air-cleaning device.

Please Note: The U.S. Environmental Protection Agency (EPA) neither certifies nor recommends particular brands of home air-cleaning devices. While some home air-cleaning devices may be useful in some circumstances, EPA makes no broad endorsement of their use, nor specific endorsement of any brand or model. This document describes the performance characteristics of several types of air cleaners sold for in-home use.

Federal pesticide law requires manufacturers of ozone generators to list an EPA establishment number on the product's packaging. This number merely identifies the facility that manufactured the product. Its presence does not imply that EPA endorses the product, nor does it imply that EPA has found the product to be safe or effective.

Some portable air cleaners sold in the consumer market are ENERGY STAR® qualified. Please note the following disclaimer on their packaging: "This product earned the ENERGY STAR by meeting strict energy efficiency guidelines set by EPA. EPA does not endorse any manufacturer claims of healthier indoor air from the use of this product."

INDOOR AIR POLLUTANTS

There are two categories of indoor air pollutants that can affect the quality of air in a home: particulate matter and gaseous pollutants.

Particulate matter (PM) is composed of microscopic solids, liquid droplets, or a mixture of solids and liquid droplets suspended in air. Also known as particle pollution, PM is made up of a number of components, including acids such as nitric and sulfuric acids, organic chemicals, metals, soil or dust particles, and biological contaminants. Among the particles that can be found in a home are:

- Dust as solid PM or fumes and smoke, which are mixtures of solid and liquid particles.
- Biological contaminants, including viruses, bacteria, pollen, molds, dust mite and cockroach body parts and droppings, and animal dander.

Particles come in a wide range of sizes. Small particles can be fine or coarse. Of primary concern from a health standpoint are fine particles that have a diameter of 2.5 micrometers (μm) or less. These particles (described as "respirable") can be inhaled; they penetrate deep into the lungs where they may cause acute or chronic health effects. Coarse particles, between 2.5 and 10 μm in diameter, usually do not penetrate as far into the lungs; they tend to settle in the upper respiratory tract. Large particles are greater than 10 μm in diameter, or roughly one-sixth the width of a human hair. They can be trapped in the nose and throat and expelled by coughing, sneezing, or swallowing.

Respirable particles are directly emitted into indoor air from a variety of sources including tobacco smoke, ozone reactions with emissions from indoor sources of organic compounds, chimneys and flues that are improperly installed or maintained, unvented combustion appliances such as gas stoves and kerosene or gas space heaters, woodstoves, and fireplaces. This category of particles also includes viruses and some bacteria.

Among the smaller biological particles found in a home are some bacteria, mold fragments and spores, a significant fraction of cat and dog dander, and a small portion of dust mite body parts and droppings. Larger particles include dust, pollen, some mold fragments and spores, a smaller fraction of cat and dog dander, a significant fraction of dust mite body parts and cockroach body parts and droppings, and skin flakes.

Gaseous pollutants include combustion gases and organic chemicals that are not attached to particles. Hundreds of gaseous pollutants have been detected in indoor air.

Sources of indoor combustion gases such as carbon monoxide and nitrogen dioxide include combustion appliances, tobacco smoke, and vehicles whose exhaust infiltrates from attached garages or the outdoors.

Sources of airborne gaseous organic compounds include tobacco smoke, building materials and furnishings, and products such as paints, adhesives, dyes, solvents, caulks, cleaners, deodorizers, cleaning chemicals, waxes, hobby and craft materials, and pesticides. Organic compounds may also come from cooking food; from human, plant, and animal metabolic processes; and from outdoor sources. Some electronic air cleaners and laser printers may generate the lung irritant ozone by design or as a by-product.

Radon is a colorless, odorless, radioactive gas that can be found in indoor air. It comes from uranium in natural sources such as rock, soil, ground water, natural gas, and mineral building materials. As uranium breaks down, it releases radon, which in turn produces short-lived radioactive particles called "progeny," some of which attach to dust particles. Radon progeny may deposit in the lungs and irradiate respiratory tissues. Radon typically moves through the ground and into a home through cracks and holes in the foundation. Radon may also be present in well water and can be released into the air when that water is used for showering and other household activities. In a small number of homes, building materials also can give off radon.[1]

THREE STRATEGIES TO REDUCE INDOOR AIR POLLUTANTS

Three basic strategies to reduce pollutant concentrations in indoor air are source control, ventilation, and air cleaning.

Source control eliminates individual sources of pollutants or reduces their emission. It is usually the most effective strategy for reducing pollutants. There are many sources of pollutants in the home that can be controlled or removed.[2] For example, solid wood or alternative materials can be used in place of pressed wood products that are likely to be significant sources of formaldehyde. Smokers can smoke outdoors. Combustion appliances can be adjusted to decrease their emissions.

Ventilation is also a strategy for decreasing indoor air pollutant concentrations. It exchanges air between the inside and outside of a building. The introduction of outdoor air is important for good air quality. In a process known as infiltration, outdoor air flows into the house through openings, joints, and cracks in walls, floors, and ceilings, and around windows and doors. Natural ventilation describes air movement through open windows and doors. Most residential forced air-heating systems and air-conditioning systems do not bring outdoor air into the house mechanically. Two primary ventilation methods can be used in most homes: general ventilation and local ventilation.

- ***General ventilation*** of the living space, by way of infiltration, natural ventilation, or mechanical ventilation, brings outdoor air indoors, circulates air throughout the home, and exhausts polluted air outdoors. Although limited by weather conditions, this method removes or dilutes indoor airborne pollutants, thereby reducing the level of contaminants and improving indoor air quality (IAQ). Special consideration should be given to the outdoor air used for ventilation. It should be of acceptable quality and should not contain pollutants in quantities that would be considered objectionable or harmful if introduced indoors. The use of ventilation to reduce indoor air pollutants should be evaluated carefully where there may be outdoor sources of pollutants.
- ***Localized ventilation*** by means of exhaust fans in bathrooms and kitchens, and in some cases by open windows and doors, removes excess moisture and strong, local pollutants and keeps them from spreading to other areas. Using exhaust fans increases the amount of outdoor air that enters a house.

Advanced designs for new homes are starting to add a mechanical feature that brings outdoor air into the home through the HVAC system. Some of these designs include energy efficient heat recovery ventilators to mitigate the cost of cooling and heating this air during the summer and winter. [3,4]

The use of air cleaners alone cannot ensure adequate air quality.

Air cleaning may be useful when used along with source control and ventilation, but it is not a substitute for either method. The use of air cleaners alone cannot ensure adequate air quality, particularly where significant sources are present and ventilation is insufficient. While air cleaning may help control the levels of airborne particles including those associated with allergens and, in some cases, gaseous pollutants in a home, air cleaning may not decrease adverse health effects from indoor air pollutants.

TYPES OF AIR CLEANERS

Various technologies can be used in air-cleaning devices. Filtration and electrostatic attraction are effective in removing airborne particles. Adsorption or chemisorption captures some gaseous and vaporous contaminants. Some air cleaners use ultraviolet light (UV) technology. Ultraviolet germicidal irradiation (UVGI) has been used to kill some microorganisms growing on surfaces. Photocatalytic oxidation (PCO), another UV light technology under development, has the potential to destroy gaseous contaminants. Ozone-generating devices sold as air cleaners use UV light or corona discharge and are meant to control indoor air pollutants.

Table 1 provides a brief summary of air-cleaning technologies and the pollutants they are designed to control.

Some air-cleaning devices are designed to be installed in the ductwork of HVAC systems or to be used in portable, stand-alone units.

In-duct or **whole-house air-cleaning devices** typically are installed in the return ducts of HVAC systems, as shown in Figure 1. The typical furnace air filter is a simple air cleaner that captures particles in the airstream to protect fan motors, heat exchangers, and ducts from soiling. Such filters are not designed to improve indoor air quality, but the HVAC system can be upgraded by using more efficient air filters to trap additional particles. Other air-cleaning devices such as electrostatic precipitators, UV lamps, and gas-phase filters use sorption and chemical reaction and are sometimes used in the ductwork of home HVAC systems.

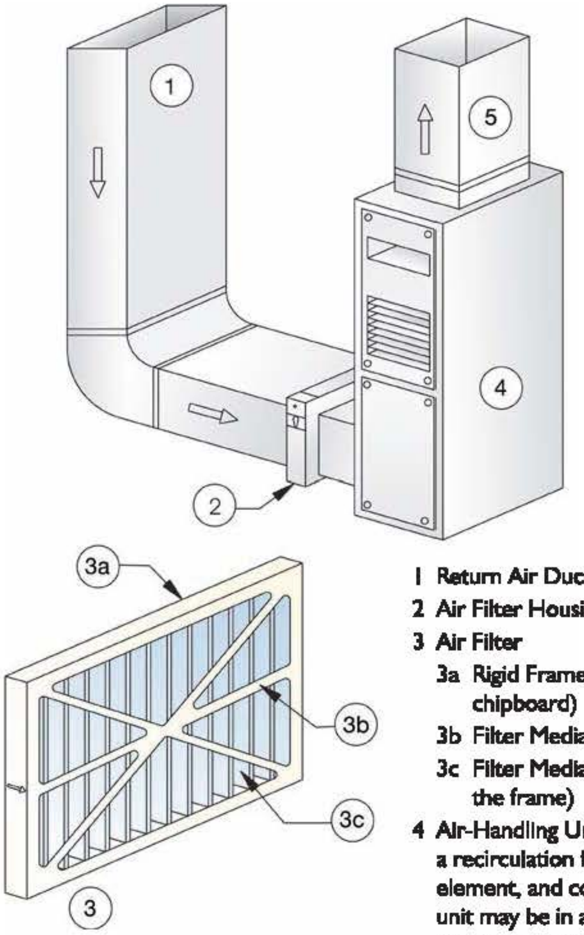
The fans in residential HVAC systems may operate intermittently or continuously. Continuous operation improves air circulation and air cleaning, but this operation mode also increases electrical energy consumption and costs.[5]

Portable air cleaners are available as small tabletop units and larger console units. They are used to clean the air in a single room, but not in an entire house. The units can be moved to wherever continuous and localized air cleaning is needed. Larger console units may be useful in houses that are not equipped with forced air-heating systems and air-conditioning systems. Portable air cleaners generally have a fan to circulate the air and a cleaning device such as a mechanical air filter, electrostatic precipitator, ion generator, or UV lamp. Some units marketed as having the quietest operation may have no fan; however, units that do not have a fan typically are

TABLE 1: SUMMARY OF AIR-CLEANING TECHNOLOGIES

AIR-CLEANING TECHNOLOGIES		POLLUTANTS ADDRESSED	LIMITATIONS
Filtration	Air filters	Particles	Ineffective in removing larger particles because most settle quickly from the air and never reach the filters.
	Gas-phase filters	Gases	Used much less frequently in homes than particle air filters. The lifetime for removing pollutants may be short.
Other Air Cleaners	UVGI	Biologicals	Bacterial and mold spores tend to be resistant to UV radiation and require more light, longer exposures to UV light, or both to be killed.
	PCO	Gases	Application for homes is limited because currently available catalysts are ineffective in destroying gaseous pollutants in indoor air.
	Ozone generators	Particles, gases, biologicals	Sold as air cleaners, they are not always safe and effective in removing pollutants. By design they produce ozone, a lung irritant.

FIGURE 1: TYPICAL AIR FILTER INSTALLATION



1 Return Air Duct
2 Air Filter Housing
3 Air Filter
 3a Rigid Frame (such as a chipboard)
 3b Filter Media Restrainer
 3c Filter Media (installed inside the frame)
4 Air-Handling Unit that contains a recirculation fan, heating element, and cooling coil. (The unit may be in a basement, closet, or attic.)
5 Supply Air Duct

much less effective than units that have one. Air cleaners may also have a panel filter with bonded fine particles of activated carbon, or an activated carbon filter encased in a frame, to remove gases and odors. Some portable air cleaners referred to as hybrid air cleaners use a combination of two or more of the devices discussed above.

In this publication, air cleaners are categorized by the types of pollutants, particulate and gaseous, that the devices are designed to remove or destroy.[6,7]

Removal of Particles

Air filters are designed to remove particulate pollutants from indoor air. Their performance depends not only on the airflow rate through the filter media and the filter efficiency, but also on factors such as the:

- Particle size and mass.
- Amount of dust on the air filter.
- Airflow rate, velocity, path, and resistance through the filter media.
- Mixing of air leaving the filter with the air in the room.
- Leakage rate of air that bypasses the air filter.

Types of Particle-Removal Air Filters

Two general types of particle removal air-cleaning devices are available: mechanical air filters and electronic air cleaners. They are classified by the method employed to remove particles of various sizes from the air.

Mechanical air filters installed in a central HVAC system or in a portable air cleaner capture particles on filter media. Particles either become trapped in the fibers of the filter or stick to the filter because of an electrostatic charge. Mechanical air filters come in two major types: flat and pleated.

Flat or *panel filters* generally consist of coarse glass fibers, coated animal hair, vegetable fibers, synthetic fibers (such as polyester or nylon), synthetic foams, metallic wools, or expanded metals and foils. The filter media may be treated with a viscous substance, such as oil, that causes particles to stick to the fibers. Flat filters also may be made of three types of permanently electrostatically charged material: resin wool, a plastic film or fiber called "electret," or an electrostatically sprayed polymer. Their static charge attracts and captures particles. The fibers of electret filters are somewhat larger than the fibers of other flat filters, resulting in relatively low pressure drop and greater efficiency in filtering smaller particles. The efficiency of electret filters decreases as the media become loaded with particles.

Pleated or *extended surface filters* are generally more efficient than flat filters in capturing respirable particles. Pleating the filter medium increases surface area, reduces air velocity, and allows the use of smaller fibers and increased packing density of the filter without a large drop in airflow rate.

A wire frame in the form of a pocket or V-shaped cardboard separators may be used to maintain the pleat spacing. The media used in pleated filters are fiber mats, bonded glass fibers, synthetic fibers, cellulose fibers, wool felt, and other cotton-polyester material blends.

High efficiency particulate air (HEPA) filters are a type of extended surface filter. HEPA filters usually are made of submicron glass fibers and have a texture similar to blotter paper. They also have a larger surface area and remove respirable particles more efficiently than pleated filters.

Electronic air cleaners use a process called electrostatic attraction to trap charged particles. There are two types of electronic air cleaners: electrostatic precipitators and ion generators.

Electrostatic precipitators have an ionization section and a collecting plate section, both of which use an external power source. The air cleaner draws air through the ionization section, where particles obtain an electrical charge. The charged particles accumulate on a series of flat plates called a collector that is oppositely charged. Cleaning the collector plates is essential to maintaining adequate performance.

Ion generators, or ionizers, disperse charged ions into the air, similar to an electrostatic precipitator, but ionizers do not have collecting plates. They produce ions by means of corona discharge or UV light. The ions attach to particles and give them a charge so they adhere to nearby surfaces such as walls, furniture, and draperies, or combine with other particles and settle on room surfaces. Ion generators are the simplest form of electronic air cleaner and come in tabletop, portable, and ceiling mounted units.

Like mechanical filters, electronic air cleaners can be installed in HVAC systems or used in portable units. Although electronic air cleaners remove small particles, they do not remove gases or odors. And because electronic air cleaners use high voltage to generate ionized fields, they can produce ozone, either as a by-product or by design.[8] Residential indoor ozone concentrations may be affected by the amount of ozone emitted by electronic air cleaners, which varies among models. Even at concentrations below public health standards, ozone reacts with chemicals emitted by such common indoor sources as household cleaning products, air fresheners, deodorizers, certain paints, polishes, wood flooring, carpets, and linoleum. The chemical reactions produce harmful by-products that may be associated with adverse health effects in some sensitive populations. The ozone reaction by-products that may result include ultrafine particles (smaller than 0.1 µm in diameter), formaldehyde, ketones, and organic acids.[8, 9, 10] Concerns about ozone and ozone-generating devices are discussed in the EPA document *Ozone Generators that are Sold as Air Cleaners*, posted on the EPA Web site at www.epa.gov/iaq/pubs/ozonegen.html.

Defining Efficiency and Effectiveness

To choose air-cleaning devices and use them properly, it is important to understand the difference between efficiency and effectiveness. The efficiency of an air-cleaning device, usually expressed as a percentage, is a measure of its ability to remove airborne particles or gaseous pollutants from the air that passes through it. The effectiveness of an air-cleaning device is a measure of its ability to reduce airborne particle or gaseous pollutant concentrations in an occupied space.

The efficiency of air filters used in ducts of HVAC systems or in portable air cleaners varies based on the airflow rate and the particulate matter load. The effectiveness of an air-cleaning device in removing pollutants from an occupied space depends on three factors: its efficiency, the amount of air being filtered, and the path that the clean air follows after it leaves the filter. For example, a filter may remove 99 percent of the particles from the air that passes through it (i.e., have 99 percent efficiency). However, if the airflow rate through the filter is only 10 cubic feet per minute (cfm) in a typical room of approximately 1,000 cubic feet (e.g., 10' x 12' x 8'), the filter will be relatively ineffective at removing particles from the air (i.e., 10 times less effective than if the airflow rate were 100 cfm).

Higher efficiency filters remove larger and smaller airborne particles more efficiently. Homeowners should take care to properly install them in HVAC systems and make sure that leakage of air bypassing the filter is minimized. The higher a filter's efficiency, the more attention must be paid to its sealed installation because increased airflow resistance is more likely to create leaks. Air filter effectiveness may be substantially reduced if air leaks through a poorly installed filter frame and its holding system.[11, 12] Leakage of air bypassing a HEPA filter used in a portable, stand-alone unit may also reduce the filter's expected efficiency. Effectiveness may be decreased if air exiting an exhaust grille of the HVAC system is not well mixed with room air before re-entering the system. This situation can occur if air return and intake vents are too close together.

Air Filters - Available Guidance for Their Comparison

Several standardized methods have been developed to measure the efficiency of different types of air filters installed in the ductwork of HVAC systems. They can be used to compare the performance of air filters made by different companies. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) and the Institute of Environmental Sciences and Technology (IEST) have published voluntary standards for rating air filters. The IEST is now the recognized standard-setting organization for the former Military Standard 282 developed by the U.S Department of Defense for rating HEPA filters. The standards do not rate the air filters' effectiveness; rather, they compare the performance of various filters.

Particle removal efficiency can be assessed by four standard methods: the weight arrestance test, atmospheric dust spot efficiency test, dioctyl phthalate (DOP) penetration test, and particle size removal efficiency (PSE) test.

The **weight arrestance test,**[13] defined in ASHRAE Standard 52.1-1992, * is generally used to evaluate low efficiency filters designed to remove the largest and heaviest particles. These filters are commonly used in residential furnaces and air-conditioning systems to protect system components, or as upstream filters to protect higher efficiency filters. In this test, a synthetic dust is fed into the air cleaner and the percentage by weight of the dust the filter traps, called "arrestance," is determined. The weight arrestance test may be of limited value in assessing the removal of smaller, respirable particles because particles in the test dust are generally larger than those that can be inhaled deeply into the lungs.

The **atmospheric dust spot efficiency test,**[13] also defined in ASHRAE Standard 52.1-1992,* is generally used to rate medium-efficiency filters in removing fine airborne dust particles that can soil walls and other interior surfaces. A naturally occurring atmospheric dust is fed into the air cleaner to test its ability to reduce soiling of a clean paper target as an indication of the cleaner's capability to remove fine particles from the air.

The **DOP penetration test,**[14] described in the IEST-RP CC001.4 test method, is used to rate true HEPA filters. A DOP cloud of uniform 0.3 µm particles is fed into the filter. The concentration of penetrating smoke measured upstream and downstream of the filter determines the filter efficiency, or the percentage of particles the filter removes.

The **PSE test,**[15] described in ASHRAE Standard 52.2-2007, provides a composite minimum efficiency for removing particles of specific size by filters incrementally loaded with synthetic dust. The PSE test method does not eliminate the need for DOP penetration and arrestance testing. Very low-efficiency air filters, such as furnace filters, must also be tested in accordance with the weight arrestance method. The composite minimum efficiency values are averaged and used to determine the air cleaner's minimum efficiency reporting value (MERV). The MERV ranges from a low of 1 to a high of 20. The PSE test

*ASHRAE Standard 52.1.1992, *Gravimetric and Dust-Spot Procedures for Method of Testing Air-Cleaning Devices Used in General Ventilation for Removing Particulate Matter* was withdrawn in spring 2009. Information previously found in this standard is now included via Addendum B to ANSI/ASHRAE Standard 52.2, *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size.* The addendum mandates calculation of weight arrestance for filters with Minimum Efficiency Reporting Values (MERVs) of 1 to 4 and atmospheric dust spot efficiency for filters with MERVs of 5 to 16.

TABLE 2: MINIMUM EFFICIENCY REPORTING VALUE (MERV) PARAMETERS

ASHRAE Standard 52.2				ASHRAE Standard 52.1	Application Guidelines		
MERV	Particle Size Removal Efficiency, Percent in Particle Size Range, µm			Dust-Spot Efficiency Percent	Particle Size and Typical Controlled Contaminant	Typical Applications	Typical Air Filter/Cleaner Type
	0.3 to 1	1 to 3	3 to 10				
20	≥ 99.999	In 0.1 – 0.2 µm particle size		—	< 0.3 µm Virus (unattached) Carbon dust Sea salt All combustion smoke	Electronics manufacturing Pharmaceutical manufacturing Carcinogenic materials	HEPA/ULPA Filters*
19	≥ 99.999	in 0.3 µm particle size		—			
18	≥ 99.99			—			
17	≥ 99.97			—			
16	> 95	> 95	> 95	—	0.3-1 µm All bacteria Droplet nuclei (sneeze) Cooking oil Most smoke Insecticide dust Most face powder Most paint pigments	Superior commercial buildings Hospital inpatient care General surgery	**Bag Filters** – Nonsupported (flexible) microfine fiberglass or synthetic media, 12 to 36 inches deep. **Box Filters** – Rigid style cartridge, 6 to 12 inches deep.
15	85-95	> 90	> 90	> 95			
14	75-85	> 90	> 90	90-95			
13	< 75	> 90	> 90	80-90			
12	—	> 80	> 90	70-75	1-3 µm Legionella Humidifier dust Lead dust Milled flour Auto emission particles Nebulizer drops	Superior residential Better commercial buildings Hospital laboratories	**Pleated filters** –Extended surface with cotton or polyester media or both, 1 to 6 inches thick. **Box Filters** – Rigid style cartridge, 6 to 12 inches deep.
11	—	65-80	> 85	60-65			
10	—	50-65	> 85	50-55			
9	—	< 50	> 85	40-45			
8	—	—	> 70	30-35	3-10 µm Mold Spores Dust mite body parts and droppings Cat and dog dander Hair spray Fabric protector Dusting aids Pudding mix Powdered milk	Better residential Commercial buildings Industrial workplaces	**Pleated filters** –Extended surface with cotton or polyester media or both, 1 to 6 inches thick. **Cartridge filters** –Viscous cube or pocket filters **Throwaway** –Synthetic media panel filters
7	—	—	50-70	25-30			
6**	—	—	35-50	< 20			
5	—	—	20-35	< 20			
4	—	—	< 20	< 20	> 10 µm Pollen Dust mites Cockroach body parts and droppings Spanish moss Sanding dust Spray paint dust Textile fibers Carpet fibers	Minimum filtration Residential window air conditioners	**Throwaway** – Fiberglass or synthetic media panel, 1 inch thick. **Washable** – Aluminum mesh, foam rubber panel **Electrostatic** – Self-charging (passive) woven polycarbonate panel
3	—	—	< 20	< 20			
2	—	—	< 20	< 20			
1	—	—	< 20	< 20			

This table is adapted from ANSI/ASHRAE Standard 52.2-2007. [15]

**The last four MERV values of 17 to 20 are not part of the official standard test, but have been added by ASHRAE for comparison purposes. Ultra Low Penetration Air filters (ULPA) have a minimum efficiency of 99.999 percent in removing 0.3 µm particles, based on the IEST test method. MERVs between 17 and 19 are rated for 0.3µm particles, whereas a MERV of 20 is rated for 0.1 to 0.2 µm particles.*

*** For residential applications, the ANSI/ASHRAE Standard 62.2-2007[16] requires a filter with a designated minimum efficiency of MERV 6 or better.*

may not be appropriate for evaluating electronic air cleaners because the dust used contains conductive carbon, which may cause electrical shorting and thus compromise the effectiveness of these devices and alter their MERV. The dust-loading procedure may also affect the efficiency of electrostatically charged filters.

A cross-reference of atmospheric dust spot efficiency tests to the MERV is shown in Table 2. This table shows the minimum PSE in three size ranges for each MERV. A consumer can use the table to identify the MERV required to control a specific pollutant. While these standards cannot by themselves predict the actual effectiveness of any filter over its lifetime, they can generally be used to compare the performance characteristics of one air filter with another.

Air Filters - Available Evidence of Their Usefulness

Whether installed in the ducts of HVAC systems or used in portable air cleaners, most air filters have a good efficiency rating for removing larger particles when they remain airborne. These particles include dust, pollen, some molds, animal dander, and those that contain dust mite and cockroach body parts and droppings. But because these particles settle rather rapidly from the air, air filters are somewhat ineffective in removing them from indoor areas. And although human activities such as walking and vacuuming, or the high velocity air exiting supply vents, can re-suspend particles, most of the larger particles will resettle before they enter the HVAC system or portable air cleaner and are removed by a particle air filter.

Large particles settle from the air rapidly; therefore, air filters are somewhat ineffective in their removal.

The appropriate type of particle removal air filter can be chosen by looking at its MERV rating in removing airborne particles from the airstream that passes through it. MERV ratings can also be used to compare air filters made by different manufacturers.

Flat or **panel air filters** with a MERV of 1 to 4 have low efficiency on smaller airborne particles, but reasonable efficiency on large particles when they remain airborne. These filters have low airflow resistance and are relatively inexpensive. Typically ½ to 1 inch thick, they are commonly used in residential furnaces and air-conditioning systems, and they are often used as pre-filters for higher efficiency filters. For the most part, such filters are used to protect the HVAC equipment from the buildup of unwanted materials on fan motors, heat exchangers, and other surfaces.

Pleated or **extended surface filters** with a MERV of 5 to 13 have higher efficiency ratings than panel filters. These medium-efficiency filters are reasonably efficient at removing small-to-large airborne particles. The airflow resistance of these filters does not necessarily increase as the MERV increases. Higher efficiency filters with a MERV of 14 to 16 have a higher average resistance to airflow than medium-efficiency filters. Higher efficiency pleated filters, sometimes inaccurately called "high efficiency," "HEPA," or "HEPA-type" filters, are similar in appearance to true HEPA filters, which have MERV values of 17 to 20, but use less efficient filter media.

The depth of these pleated or extended surface filters may vary from approximately 1 to 6 inches for medium-efficiency models and 6 to 12 inches for higher efficiency filters. As the depth and pleating increases, so does the area of the filtration medium, helping to offset the increase in resistance to airflow across the filter. Because of their increased surface area, these filters often have an extended life. The operating resistance of a fully dust-loaded filter must be considered in the design, because it is the maximum resistance against which the fan operates. Generally, dust loading results in increased filtration efficiency along with an increase in pressure drop. Pressure drop in media-type filters is greater than that in electronic-type cleaners and slowly increases over the filters' useful life.

Some residential HVAC systems may not have enough fan or motor capacity to accommodate higher efficiency filters. Therefore, the HVAC manufacturer's information should be checked prior to upgrading filters to determine whether it is feasible to use more efficient filters.

True **HEPA filters** with a MERV between 17 and 19 are defined by the IEST test method as having a minimum efficiency between 99.97 percent and 99.999 percent in removing 0.3 µm particles. A MERV of 20 is rated for 0.1 to 0.2 µm particles. HEPA filters have higher efficiencies for removing both larger and smaller airborne particles. True HEPA filters normally are not installed in residential HVAC systems; installing a HEPA filter in an existing HVAC system would probably require professional modification of the system. A typical residential air-handling unit and the associated ductwork would not be able to accommodate such filters because of their size and increased airflow resistance. Specially built high performance homes may occasionally be equipped with true HEPA filters installed in a properly designed HVAC system.

Manufacturers market HEPA filters to allergy and asthma patients. Experimental data and theoretical predictions indicate that medium-efficiency air filters, MERV between 7 and 13, are likely to be almost as effective as true HEPA filters in reducing the concentrations of most indoor particles linked to health effects.[17] Available data indicate that even for very small particles, HEPA filters are not necessarily the preferred option. For these small particles, relatively large decreases in indoor concentrations (around 80 percent) are attainable with medium filter efficiency (such as a MERV of 13). Increasing filter efficiency above a MERV of 13 results in only modest predicted decreases in indoor concentrations of these particles.* Predicted reductions in indoor concentrations of cat and dust mite allergens carried on small particles vary from 20 percent with a MERV 7 filter to 60 percent using a HEPA filter. Increasing filter efficiency above a MERV of 11 does not significantly reduce predicted indoor concentrations of animal dander. Medium-efficiency air filters are generally less expensive than HEPA filters and allow quieter HVAC fan operation and higher airflow rates than HEPA filters because they have less airflow resistance. Pleated filters 1 to 2 inches thick that have a MERV of 12 are available for use in homes and may often be installed without modifying residential HVAC systems; however, manufacturer's information should be checked prior to installation.

Filters that have a MERV between 7 and 13 are likely to be nearly as effective as true HEPA filters.

Electrostatic precipitators remove and collect small airborne particles and have an initial ASHRAE dust spot efficiency of up to 98 percent at low airflow velocity. This efficiency will be highest for clean electronic air cleaners. Electronic air cleaners exhibit high initial efficiencies in cleaning air, largely because of their ability to remove fine particles. Their efficiency decreases as the collecting plates become loaded with particles, or as airflow velocity increases or becomes less uniform.

Portable Air Cleaners - Available Guidance for Their Comparison

The effectiveness of a portable air cleaner depends on the air-cleaning device's efficiency in removing airborne pollutants, the quantity of air being filtered, the particle size, the size of the room the air cleaner serves, and its location in the space. A voluntary standard is available for measuring the effectiveness of portable air cleaners in reducing airborne pollutants in a room. It was developed by the Association of Home Appliance Manufacturers (AHAM), a private voluntary standard-setting trade association, and is recognized by the American National Standards Institute.[18] The standard compares the effectiveness of portable

*Some air filters may be effective at reducing tobacco smoke particles, but they will not remove gaseous pollutants from tobacco smoke. While some gas-phase filters may remove specific gaseous pollutants from the complex mixture of chemical compounds in tobacco smoke, none is expected to remove all unwanted gaseous combustion products. Odorous and toxic organic gases may also evaporate from liquid tobacco smoke particles trapped by the air filter.[12]

air cleaners in a room size test chamber, measured by the clean air delivery rate (CADR) for each of three types of particles in indoor air: dust, tobacco smoke, and pollen. Although AHAM uses tobacco smoke particles to represent smaller airborne particles, air cleaning should not be construed as an effective way to address environmental tobacco smoke. There are thousands of particulate and gaseous chemical compounds, including many known carcinogens, in tobacco smoke that cannot be removed effectively by air cleaning.

Although AHAM uses the CADR concept to evaluate the performance of portable air cleaners in reducing particulate matter concentrations, the CADR can be applied equally to the removal of gaseous pollutants. The CADR does not apply to whole-house air-cleaning devices installed in HVAC ductwork.

The CADR is a measure of a portable air cleaner's delivery of contaminant-free air, expressed in cubic feet per minute. For example, an air cleaner that has a CADR of 250 for dust particles can reduce dust particle levels to the same concentration as would be achieved by adding 250 cfm of clean air. The portable air cleaner's removal rate competes with other removal processes occurring in the space, including deposition of particles on surfaces, sorption of gases, indoor air chemical reactions, and outdoor air exchange. While a portable air cleaner may not achieve its rated CADR under all circumstances, the CADR value does allow comparisons among portable air cleaners.

AHAM has a portable air-cleaner certification program and lists all certified cleaners and their CADRs on its Web site at www.cadr.org.[19] AHAM's online directory of certified portable air cleaners allows searches by certified CADR ratings, suggested room size, manufacturer, or brand name. The CADR values reported for selected portable air cleaners are based on an 80-percent reduction in steady particle concentrations. AHAM's recommended effectiveness of 80 percent produces meaningful reductions in contaminant concentrations indoors. This level of effectiveness corresponds to an air cleaner's capability to provide an amount of clean air that is four to five times the volume of the specified size room.[9]

Indoor particle concentrations are not always constant over time. Some indoor pollutants might be produced periodically from sources such as hobby and craft materials or cooking food. These intermittent pollutant sources have only a modest effect on particle concentrations indoors compared to sources of steady pollutant concentrations.

Some portable air cleaners sold to consumers are ENERGY STAR® qualified. Earning the ENERGY STAR means a product meets strict energy efficiency guidelines set by EPA and the U.S. Department of Energy. The ENERGY STAR disclaimer label, which includes the following statement, is placed on the product packaging of ENERGY STAR qualified air cleaners: "This product earned the ENERGY STAR by meeting strict energy efficiency guidelines set by the US EPA. US EPA does not endorse any manufacturer claims of healthier indoor air from the use of this product."

Most portable air cleaners don't effectively remove large particles such as dust, pollen, some mold spores, and particles containing dust mite and cockroach allergens in rooms of typical size.

Portable Air Cleaners - Available Evidence of Their Usefulness

Many of the portable air cleaners AHAM tested have moderate-to-large CADR ratings for small particles when used in rooms of appropriate size.[9] However, for typical room sizes, most portable air cleaners currently on the market do not have high enough CADR values to remove effectively large particles such as dust, pollen, some mold spores, animal dander, and particles containing dust mite and cockroach allergens. Some portable air cleaners that use electronic air cleaners may produce ozone, which is a lung irritant.

Studies have assessed portable air cleaners' performance in removing airborne particles as well as their limited clinical effects. Some tests addressed the removal of tobacco smoke particles.[20, 21, 22] Limited testing on larger airborne particles including those that contain cat, dog, and dust mite allergens have also been performed.[23, 24, 25, 26, 27, 28] Many experimental studies used portable air cleaners equipped with HEPA filters, but the available sources indicate that HEPA filters may not be preferable to medium-efficiency filters because of HEPA filters' lower air delivery due to air bypassing the filter and to higher resistance to airflow. In addition, portable air cleaners are not effective at removing large particles because large particles settle out of indoor air at a substantial rate.

The effectiveness of portable air cleaners in removing particles from indoor air depends on the size of the particles. One paper[9] reported that air-cleaning effectiveness of at least 80 percent can be achieved by portable air cleaners that have moderate-to-high CADR ratings in homes where small particles are the main concern. On the other hand, for larger airborne particles, the combination of small room size and high CADR ratings may yield particle removal effectiveness of 80 percent or more. However, for typical rooms larger than 200 square feet, most portable air cleaners on the market do not have high enough CADR values to remove large particles effectively. This fact may account for the finding that portable air cleaners are most likely to be effective in reducing indoor concentrations of smaller airborne particles such as those associated with cat or dust mite allergens.[26] However, air cleaning was not found to be consistently and highly effective in reducing respiratory symptoms since much of the airborne allergens appear to be carried on larger particles.[26]

Some manufacturers consider their hybrid portable air cleaners, which use multiple air-cleaning devices, to be more effective than portable air cleaners that use a single device. However, the effectiveness of these hybrid units may suffer because more air cleaners arranged in a series may mean increased air resistance, which could decrease air delivery or cause air to bypass the cleaner. Effectiveness may also be decreased if air exiting the portable air cleaner outlet is not adequately mixed with room air before re-entering the unit.

Useful information about portable air cleaners is available from *Consumer Reports* magazine. Published by Consumers Union, an independent, nonprofit organization, *Consumer Reports* provides an annual review of products, their updated reports, and ratings. The test method used by Consumers Union is not intended to be the basis for a standard for evaluating the performance of air-cleaning devices; rather, Consumers Union tests air cleaners using its own testing procedures, rates the cleaners based on a variety of criteria, and ranks them in charts that are easy to understand. According to Consumers Union, some portable air cleaners that use electrostatic precipitators may produce measurable amounts of ozone as a by-product.[29] Electrostatic precipitators may also make a crackling sound as they accumulate dirt.

The placement of any portable air cleaner may affect its performance. If there is a specific, identifiable source of pollutants, the unit should be placed so its intake is near that source. If there is no specific source, the air cleaner should be placed where it will force clean air into occupied areas. It should not be situated where walls, furniture, and other obstructions will block the intake and outlet. A portable air cleaner will be much more effective when all the doors and windows in a room are closed. If the door to a room where a portable air cleaner is located is open, or if the HVAC system is operating, the room air often will mix with air from throughout the house, and the air cleaner will not reduce the particle concentrations in the room as intended.

Removal of Gaseous Pollutants by Sorbents

Many different gas-phase air-filtration devices are available; however, comparing and rating the effectiveness of installed sorbent filters is difficult because there is no standard test method.

ASHRAE Standard Project Committee 145 is developing a standard method for evaluating the effectiveness of gas-phase filtration devices installed in the ductwork of residential HVAC systems, but not in portable air cleaners.[30]

Gas-phase air filters remove gases and odors by either physical or chemical processes. These filters typically are designed to remove one or more of the gaseous pollutants present at low concentrations in the airstream that passes through them. They are not, however, designed to eliminate all gaseous pollutants. Air cleaners that do not contain sorbent materials or photocatalytic oxidation technology, discussed on page 20, will not remove gaseous pollutants.

A sorbent filter's behavior depends on many factors that can affect the removal of gaseous contaminants:

- Airflow rate and velocity through the sorbent.
- Concentration of contaminants.
- Presence of other gaseous contaminants.
- Total available surface area of the sorbent. (Some manufacturing techniques can significantly reduce a filter's total surface area.)
- Physical and chemical characteristics of the pollutants and the sorbent (such as weight, polarity, pore size, shape, volume, and the type and amount of chemical impregnation).
- Pressure drop.
- Removal efficiency and removal capacity.
- Temperature and relative humidity of the gas stream.

The limited lifetime of gas-phase filters may contribute to their less frequent use in home HVAC systems.

Gas-phase filters are much less common than particle air-cleaning devices in homes because a properly designed and built gas-phase filtration system is too big for a typical residential HVAC system or portable air cleaner. Other factors that may contribute to the less frequent use of gas-phase filters in home HVAC systems are the filters' limited useful life, the fact that the sorbent material must be targeted to specific contaminants, the purchase price of the filters, and the costs of adapting them to residential applications, when possible, and of operating them once they have been installed.

Types of Sorbents Used for Gaseous Pollutant Removal

There are two main processes that remove gaseous contaminants: a physical process known as adsorption and a chemical reaction called chemisorption.

Adsorption results from the physical attraction of gas or vapor molecules to a surface. All adsorbents have limited capacities and thus require frequent maintenance. An adsorbent will generally adsorb molecules for which it has the greatest affinity and will allow other molecules to remain in the airstream. Adsorption occurs more readily at lower temperatures and humidity. Solid sorbents such as activated carbon, silica gel, activated alumina, zeolites, synthetic polymers, and porous clay minerals are useful because of their large internal surface area, stability, and low cost.

Activated carbon is the most common adsorbent used in HVAC systems and portable air cleaners to remove gaseous contaminants. It has the potential to remove most hydrocarbons, many aldehydes, and organic acids. However, activated carbon is not especially effective against oxides of sulfur, hydrogen sulfide, low molecular weight aldehydes, ammonia, and nitrogen oxide.

Chemisorption occurs when gas or vapor molecules chemically react with sorbent material or with reactive agents impregnated into the sorbent. These impregnates react with gases and form stable chemical compounds that are bound to the media as organic or inorganic salts, or are broken down and released into the air as carbon dioxide, water vapor, or some material more readily adsorbed by other adsorbents. Many different chemicals may be impregnated on activated carbon; potassium permanganate

is a common chemisorbent impregnated into activated alumina. It reacts with many common air pollutants, including formaldehyde and sulfur and nitrogen oxides. Because a chemisorbent will react with only one or a limited number of reactive pollutants, it should not be expected to reduce others.

Applications of Sorbents for Gaseous Pollutant Removal

Gas-phase filters that contain sorbents may be installed in HVAC systems or in portable air cleaners. They are usually located downstream of particle air filters. The air filter reduces the amount of particulate matter that reaches the sorbent, and the sorbent collects vapors that may be generated from liquid particles that collect on the particle filter.

Some gas-phase filters may remove, at least temporarily, a portion of the gaseous pollutants in indoor air. Although some gas-phase air filters—if properly designed, used, and maintained—may effectively remove specific pollutants from indoor air, none is expected to remove adequately all of the gaseous pollutants in a typical home. For example, carbon monoxide is not readily captured by adsorption or chemisorption. In addition, gaseous-pollutant-removal systems usually have a limited lifetime before the sorbent must be replaced. There is also a concern that saturated sorbent filters may release trapped pollutants back into the airstream.[31]

Tests of gaseous pollutant removal by activated carbon generally have been conducted using only high concentrations of pollutants, so little information is available on carbon's effectiveness in removing chemicals present in the low concentrations (parts per billion [ppb]) normally found in indoor air. Tests performed at EPA measured the adsorption isotherms for three volatile organic compounds (VOCs) at concentrations of 100 ppb to 200 ppb using three samples of activated carbon. The bed depth needed to remove the compounds was estimated assuming a 150 ppb concentration in the air, an exit concentration of 50 ppb, and a flow rate of 100 cfm across a 2' x 2' filter. The results of the study suggest that breakthrough of these chemicals would occur quickly in 6-inch deep carbon filters used for odor control.[32]

Because of their compact design, particle air filters that use impregnated media are available for residential HVAC systems and portable air cleaners. They use sorbent particles of carbon, permanganate alumina, or zeolite incorporated into fibrous filter media. Such filters generally range from $^1/_8$ inch to 2 inches thick. They provide a combination of particulate and gas-phase filtration with a minor increase in pressure drop across the filter. Their use in an existing HVAC system does not require extensive or expensive modifications to the system. However, their useful service life varies according to indoor pollution concentrations and exposure time. Breakthrough of the contaminants back into the room takes place very quickly in the thin layer impregnated with sorbents, resulting in a much shorter service life for the filter, which must be replaced frequently. Thus, these devices usually have limited effectiveness in removing odors.

Removal of Radon and Its Progeny

EPA does not recommend air cleaning to reduce the health risks associated with radon and the decay products of radon gas, which are called "radon progeny." The Agency recommends the use of source control technologies to prevent radon from entering residential structures. The most effective radon control technique is active soil depressurization (ASD).[1] An ASD system uses an electric fan to minimize radon entry by drawing air from under the slab/floor and venting it to the outside above the building's roofline. Another, less effective technique installed during construction is a passive radon reduction system, also known as radon-resistant new construction (RRNC).

EPA does not recommend using air cleaners to reduce the health risks associated with radon.

RRNC systems are "dual-purpose" systems. They typically do not have a fan, but if subsequent testing indicates an elevated radon level, a fan can be installed and the RRNC system will become, in effect, an ASD system.

A limited number of studies have investigated air cleaners' effectiveness in removing radon and its progeny. They compared the removal efficiencies of various air cleaners, including mechanical air filters, electrostatic precipitators, and ionizers equipped with fans, and the risk reduction the air cleaners achieve. However, the degree of risk reduction found by these studies has been inconsistent.

Deactivation or Destruction of Pollutants

Three types of air cleaners on the market are designed to deactivate or destroy indoor air pollutants: ultraviolet germicidal irradiation (UVGI) cleaners, photocatalytic oxidation (PCO) cleaners, and ozone generators sold as air cleaners.

Ultraviolet Germicidal Irradiation Cleaners

UVGI cleaners are intended to improve residential IAQ by deactivating indoor biological pollutants that are airborne or growing on the moist interiors of HVAC surfaces (e.g., cooling coils, drain pans, or ductwork).

There is no standard test method to rate and compare the effectiveness of UVGI cleaners installed in either residential HVAC systems or portable air cleaners. Typical UVGI cleaners used in homes have limited effectiveness in killing bacteria and molds. The effective destruction of some viruses and most mold and bacteria spores usually requires much higher UV exposures than a typical home unit provides. Thus, UVGI does not appear to be effective as a sole control device. When UVGI is used, it should be used in addition to—not as a replacement for—conventional particle filtration systems.[33] Using UVGI in addition to HEPA filters in HVAC systems or in portable units offers only minimal infection control benefits over those provided by the HEPA filters alone.[33, 34]

Biological pollutants such as molds and bacteria enter a house by various routes, including open windows, joints and cracks in walls, and on clothing, food, or pets. Molds and some bacteria can be found in either the vegetative or the spore phase of their life cycle. Vegetative bacteria and molds are in the growth and reproductive phase; they are not spores. Some bacteria form spores, an inactive phase characterized by a thick protective coating, to survive harsh environmental conditions. Molds produce tiny spores in order to reproduce. Mold spores will germinate where moisture and nutrients are available, such as on basement walls, in refrigerators, on HVAC coils, on air filters, and in drip pans.

Mechanical air filters will capture some biological pollutants, but some will bypass the filter along with the airstream, and many small microorganisms can pass through lower efficiency filter media. Microorganisms such as bacteria and molds also can enter the HVAC system by the following mechanisms.

- They may grow through the filter media when conditions are favorable, for example when moisture is present and temperatures are high.[34, 35]
- They can be introduced into the system during routine maintenance, for example a filter change.[36]
- Mold spores on the filters can be released back to the airstream when the air velocity suddenly increases, for example during HVAC system startup or off-and-on operation.[37]

Once bacteria and mold spores are downstream of the filter, they may grow in the presence of condensation on cooling coils, drain pans, and internal thermal insulation, or on the surfaces of the air-handling unit and ductwork.

UVGI Technology

Most UV lamps used to kill germs in residential settings are low pressure mercury vapor lamps that emit UV radiation at a wavelength of 253.7 nanometers, which has been shown to have germicidal effects.[38] UV light can penetrate the outer structure of a microorganism's cell and alter its DNA, permanently preventing replication and causing cell death. But some bacterial and mold spores are resistant to UV radiation.

Types of UVGI Cleaners and Their Effectiveness

There are two types of UVGI applications: cleaners designed for airstream disinfection, to reduce the viability of microorganisms as they flow through the HVAC system or portable air cleaner, and cleaners designed for surface disinfection, to prevent the reproduction of microorganisms on specific components of an HVAC system.[38, 39]

UVGI lamps for airstream or surface disinfection usually are located in the air duct of an HVAC system downstream of the filter and upstream of the cooling coil or in a portable air cleaner downstream of the filter.

If properly designed, the UVGI cleaner in a typical **airstream disinfection** application has the potential to reduce the viability of vegetative bacteria and molds and to provide low to moderate reductions in viruses but little, if any, reduction in bacterial and mold spores.[33, 34, 40] Spores tend to be resistant to UV radiation, and killing them requires a very high dosage.[38, 41, 42]

UVGI cleaners might not reduce allergy or asthma symptoms.

When the fan in an airstream disinfection application is not operating, there is no air movement and no disinfection.

UVGI cleaners in a **surface disinfection** application are installed in air-handling units to prevent or limit the growth of vegetative bacteria and molds on moist surfaces in the HVAC system.[34, 39, 40, 43] One study reported a 99-percent reduction in microbial contaminants growing on exposed HVAC surfaces, but a reduction in airborne bacteria of only 25 to 30 percent.[44] One reason that the surface disinfection application provides only a slightly noticeable reduction in airborne microbial concentrations may be that microorganisms in the airstream are exposed to the UV light for a shorter time. Conversely, microorganisms growing on exposed HVAC surfaces are given prolonged direct UVGI exposure. Another study found that UV lamps yielded somewhat lower levels of mold in the fiberglass insulation lining the air-handling unit.[40]

Prolonged direct UVGI exposure can destroy vegetative microbial growth—but not most spores—on the surfaces of forced-ventilation units, filters, cooling coils, or drain pans. Killing molds and bacteria while they are still in the susceptible vegetative state reduces the formation of additional spores. UV radiation is ineffective in killing microorganisms if they proliferate inside the filter media, system crevices, porous thermal insulation, or sound-absorbing fibrous material liners.[39]

A review of scientific literature has shown that the effectiveness of UVGI cleaners in killing microorganisms may vary depending on UV irradiation dose, system design and application, system operation characteristics, and the microorganism targeted for deactivation. Further independent testing using a standardized test method is required before firmer conclusions can be made about the effectiveness of various UV cleaners in destroying microorganisms of concern. Some manufacturers of UVGI cleaners used in HVAC systems or portable air cleaners claim their units reduce dust mite allergens, airborne microorganisms such as viruses, bacteria, molds, and their spores, and gaseous pollutants from indoor air. However, it is likely that the effective destruction of some viruses and most mold and bacterial spores requires much higher UV exposures than a typical residential UVGI unit provides.[36, 38, 39]

No research or studies were found that show UV disinfection is effective in reducing dust mite and mold allergenicity or that UV radiation has the potential to remove gaseous pollutants. Because mold is allergenic, whether dead or alive, it can cause allergic reactions in sensitive populations. Therefore, UVGI cleaners might not be effective in reducing allergy and asthma symptoms. If mold is growing indoors, it should be removed.[45]

Planning and Maintaining a UVGI System

A number of studies [34, 36, 38, 46, 47] report that the most important performance elements of a UVGI system are the type of UV lamp and ballast, the relative humidity, temperature, air velocity, and duct reflectivity.

High output UV lamps have been found to provide higher irradiance than low-output lamps. Lamps designated for low-temperature operation also appear to perform better. Increased relative humidity is commonly believed to decrease the irradiation of UVGI; however, the literature is contradictory and incomplete. Air temperature can affect the power output of UVGI lamps if it exceeds design temperatures. Operating a UVGI system at air velocity above design will degrade the system's effectiveness. Reflectivity can be an economical way of intensifying the UVGI field in an enclosed duct. Polished aluminum is highly reflective of UV wavelengths, while typical duct liner material has little or no reflectance in the UV spectrum.

Regular maintenance of UVGI systems is crucial and usually consists of cleaning the lamps of dust and replacing old lamps. Manufacturers' recommendations regarding safety precautions, exposure criteria, maintenance, and monitoring associated with the use of UVGI systems should be followed.

By-products Generated by UVGI Systems

According to two studies,[38, 43] operating UV lamps installed in HVAC systems to irradiate the surfaces of air-handling units does not result in increased concentrations of ozone, VOCs, or other chemical by-products.

Photocatalytic Oxidation Cleaners

PCO cleaners are intended to destroy gaseous pollutants and their odors by converting them into harmless products, but they are not designed to remove particulate pollutants. PCO cleaners use a UV lamp and a photocatalyst, usually titanium dioxide, to create oxidants that destroy gaseous contaminants. When the photocatalyst is irradiated with UV light, a photochemical reaction takes place and hydroxyl radicals form. The hydroxyl radicals oxidize gaseous pollutants adsorbed on the catalyst surface. This reaction, called photocatalytic oxidation, converts organic pollutants into the carbon dioxide and water. To achieve effective conversion, the reaction rate of the PCO cleaner must match the rates of contaminant generation and infiltration rate minus the exfiltration rate (movement of the air from the space served to the outdoors).

There is no standard test method to compare and rate the effectiveness of PCO cleaners installed in residential HVAC systems or portable air cleaners. PCO is an emerging technology intended to improve residential IAQ by destroying gaseous contaminants. Although PCO is still under development, a few home air cleaners that use it are available in the United States. PCO cleaners are promoted for use in HVAC system ducts or in portable air cleaners. Some manufacturers claim PCO devices can remove tobacco smoke, microorganisms, and other indoor particulate pollutants even though the devices are not meant to remove particles.

Application of PCO cleaners for homes is limited in destroying gaseous pollutants from indoor air.

The usefulness of PCO cleaners in homes is limited because available photocatalysts (i.e., substances that react with light) are ineffective in completely destroying gaseous pollutants in indoor air.[48, 49, 50] Other application and engineering issues are not fully resolved,

including the relatively large power consumption of PCO units; the complexity of the PCO process, which combines the operation of a UV light and a catalyst; and the need to remove multiple compounds from the contaminated airstream. Some PCO cleaners fail to destroy pollutants completely and instead produce new indoor pollutants that may cause irritation of the eyes, throat, and nose. Until more data become available, information on the performance of PCO cleaners will remain limited and inconclusive.

Effectiveness of PCO Systems

One study [51] reported that PCO devices installed in portable air cleaners did not effectively remove any of the test VOCs present at the low concentrations normally found in indoor air. This study compared the VOC-removal efficiencies of 15 air cleaners that use different types of technology. A mixture of 16 VOCs commonly found indoors was used. The report indicated that the PCO devices studied might not work as advertised. The findings also showed that some devices appear not to have fully implemented PCO technology.

Ozone is a lung irritant that can cause adverse health effects.

A review of the literature suggests that more research is needed to further advance PCO as an effective technology in removing low levels of gaseous contaminants from the indoor air of residences.[49, 50, 51] This additional research should include many important performance characteristics that influence the effectiveness of PCO cleaners, such as whether:

- A decrease in light irradiance with illumination time inhibits performance.[49]
- Photocatalyst deactivation in the presence of chemicals such as toluene, benzene, ethanol, or hexamethyldisilazane decreases performance.[49, 50, 52]
- An increase in reaction temperature or water vapor content increases the PCO reaction rate.[53]
- Competitive adsorption between gaseous contaminants affects the PCO reaction mechanism.[49, 54]

Estimated costs of PCO technology are significantly higher than those of activated carbon technology. A major factor influencing PCO costs is the intensity of UV light required at the inlet to destroy a range of VOCs at the low concentrations that typify IAQ problems.[48]

PCO By-products

PCO of certain VOCs may create by-products that are indoor pollutants if the system's design parameters and catalyst metal composition do not match the compound targeted for decomposition, particularly in the presence of multiple reactive compounds commonly found in residential settings. One study reported that no detectable by-products formed during the PCO of 17 VOCs using titanium dioxide under the experimental conditions.[55] However, two studies on the degradation of 4 chlorinated VOCs found by-products including phosgene and chlorides.[56, 57] In addition, the PCO of trichloroethylene in air using titanium dioxide as the catalyst yielded as by-products carbon monoxide, phosgene, carbon dioxide, hydrogen chloride, and chlorine.

Ozone Generators

Ozone generators sold as air cleaners and marketed as in-duct or portable units use UV light or corona discharge to produce ozone, which is dispersed by a fan into occupied spaces.[8]

Some manufacturers and vendors of ozone generators suggest that ozone reacts with both chemical and biological pollutants and transforms them into harmless substances. They also often make statements and distribute materials that lead the public to believe that these devices are always safe and effective in controlling indoor air pollutants. However, ozone is an irritant gas that reacts with lung tissue and can cause asthma attacks; coughing; chest discomfort; irritation of the nose, throat, and trachea; and other adverse health effects.

As ozone reacts with chemical pollutants, it can produce harmful by-products.[8, 9, 10]

Available scientific evidence shows that, at ozone concentrations below public health standards, ozone has little potential to remove indoor air contaminants such as many odor-causing chemicals, viruses, bacteria, molds, and tobacco smoke; thus, ozone is generally ineffective in controlling indoor air pollution. Some controlled studies show that the concentration of ozone produced by ozone generators can exceed standards even when consumers follow the manufacturer's instructions. No federal agency has approved ozone generators for use in occupied spaces.

There is a large body of written material on ozone and the use of ozone indoors, but much of this material makes claims or draws conclusions without substantiation and a basis in sound science. In developing *Ozone Generators that Are Sold as Air Cleaners*, EPA reviewed a wide assortment of this literature, including information provided by a leading manufacturer of ozone-generating devices. In keeping with EPA's policy of ensuring that the information it provides is based on sound science, only peer reviewed, scientifically supported findings and conclusions were relied on in developing this document. The document is posted on the EPA Web site at www.epa.gov/iaq/pubs/ozonegen.html. The public is advised to use methods proven to be safe and effective in controlling indoor air pollution. These methods include eliminating or controlling pollutant sources and increasing outdoor air ventilation.

Federal pesticide law requires manufacturers of ozone generators to list an EPA establishment number on the product's packaging. This number merely identifies the facility that manufactured the product. The presence of this number on a product's packaging does not imply that EPA endorses the product, nor does it imply that EPA has found the product to be safe or effective.

WILL AIR CLEANING REDUCE HEALTH EFFECTS FROM INDOOR AIR POLLUTANTS?

Air-cleaning devices may help reduce levels of smaller airborne allergens, particles, or, in some cases, gaseous pollutants in a home. However, air cleaners may not decrease adverse health effects particularly in sensitive populations such as children, people with asthma and allergies, and the elderly.

Clinicians frequently recommend that patients who have asthma or allergies use HEPA air filters in HVAC systems or in portable air cleaners. Regardless of how efficient and effective air-cleaning devices are in removing pollutants, a question still remains about their ability to reduce adverse health effects.

How effectively air-cleaning devices alleviate allergic and other health symptoms remains uncertain. Strong data linking air-cleaning devices to reduced health symptoms do not exist. Many studies have associated air-cleaning devices with reductions in airborne indoor pollutant concentrations, but more clinical studies are needed to determine whether air cleaners significantly affect health outcomes. A literature review documented only a limited number of studies that attempted to evaluate the clinical outcomes of air cleaner use. These studies focused on more sensitive groups, such as asthmatic and allergic individuals, children, and the elderly. A number of the studies had important limitations, such as small study size, short duration, and lack of blinding (i.e., subjects and scientists were aware of air cleaner operation), which may result in a placebo effect. The results were also more suggestive than conclusive.

Many indoor pollutants related to asthma and allergies are either airborne particles or irritants, such as the gaseous components of secondhand smoke or nitrogen dioxide, chemicals linked with gas cooking appliances, fireplaces, wood stoves, and unvented kerosene and gas space heaters. Most studies involving subjects who have perennial and seasonal allergy or asthma symptoms tested portable air cleaners equipped with HEPA filters.

Few studies tested gas-phase filtration and air cleaners using UV light technology, such as UVGI cleaners and PCO cleaners. The scarcity of data results in little scientific evidence that these devices are associated with a reduction in health symptoms.

The effects of particle air cleaners on allergy and asthma symptoms have been reviewed by the Institute of Medicine (IOM) Committee on the Assessment of Asthma and Indoor Air of the National Academy of Sciences.[26] The IOM concluded that:

> The results of existing experimental studies are inadequate to draw firm conclusions regarding the benefits of air cleaning for asthmatic and allergic individuals…. Air cleaners are helpful in some situations in reducing allergy or asthma symptoms, particularly seasonal symptoms, but it is clear that air cleaning, as applied in the studies, is not consistently and highly effective in reducing symptoms.

The use of air cleaners may help reduce levels of smaller airborne allergens or particles, but should not be expected to effectively reduce health symptoms.

Several factors should be considered in evaluating whether an air cleaner is beneficial in alleviating health effects.

- Many studies on the health benefits of air cleaning involve multiple interventions and thus are not useful in determining the effects of air cleaners alone.

  The health benefits of air cleaners are often studied along with other interventions such as mattress and pillow covers, exclusion of pets from the bedroom, weekly baths for pets, or vacuum cleaning. Studies that consider air cleaning concurrently with other interventions have relatively little value in determining the clinical outcome resulting from the use

of air cleaners because it is not clear if any improvements demonstrated are due to the air-cleaning devices or to the other interventions.[23, 24, 25, 27, 28, 58, 59]

- An air cleaner's ability to remove some airborne pollutants, including microorganisms, is not, in itself, an indication of the air cleaner's ability to reduce health symptoms.

An air cleaner's ability to remove some airborne pollutants is not an indication of its ability to reduce health symptoms.

As discussed previously, pollen, dust mite and cockroach allergens, some mold spores, and animal dander carried on large particles settle rapidly before they can be removed by filtration. Because these particles do not remain airborne, air-cleaning devices are relatively ineffective in their removal.[9, 26, 60] Therefore, effective allergen control requires routine cleaning and dust control including the weekly washing of bed sheets, frequent vacuuming of carpets and furniture, and regular dusting and cleaning of hard surfaces. (For more on allergen control, visit www.epa.gov/asthma.)

A significant fraction of cat and dog allergens and a small portion of dust mite allergens associated with mite feces are carried on small particles. Consequently, they are more easily dispersed throughout a house, remain airborne longer, and are more likely to be removed by air cleaners.[23, 61] Although there is evidence that some air cleaners can remove a portion of smaller particles from the air, there is little evidence that these reductions in particle levels alleviate health symptoms. This lack of improvement in symptoms may be due in part to the fact that, once sensitized, allergic and asthmatic individuals respond to much lower levels of pollutants.

Air cleaning may have a useful role when used in conjunction with source control and ventilation with clean outdoor air.

There is little clinically confirmed support for the effectiveness of UVGI cleaners in reducing health symptoms in either airstream or surface applications. Despite UVGI's ability to deactivate some surface-grown microorganisms, data linking the effectiveness of UVGI systems to reduced health symptoms in sensitive populations such as children, asthmatic and allergic individuals, and the elderly are not available for residential settings.

- Some air cleaners may produce new, potentially toxic pollutants or may re-disperse old ones.

A limited number of studies report that irradiation by UVGI lamps reduce vegetative bacteria and molds that are either airborne or growing on moist HVAC surfaces.[34, 39, 40, 43, 44] However, the dead mold spores may still cause allergic reactions in some people.

High moisture and elevated temperatures can promote bacteria and mold growth in particulate filter media.[35] Air filters may re-emit bacteria and mold spores during HVAC startup and off-and-on operations when air velocity suddenly increases.[37]

Ozone generators sold as air cleaners for use in occupied indoor spaces produce ozone, a lung irritant.[8] Electronic air cleaners, such as ion generators and electrostatic precipitators, have the potential to emit potentially dangerous levels of ozone.[5, 22, 29] Contamination of electrode surfaces in electronic air cleaners may cause increased ozone levels.[62] There also have been reports of electronic air cleaners producing fine particulate material from the reaction of ozone produced in the corona discharge with other chemicals indoors.[9, 10, 63]

Liquid tobacco smoke particles trapped by an air filter may give off odorous organic gases.[12] Saturated sorbent filters may also release trapped gaseous pollutants back into the airstream.[31] If a PCO system's design parameters

do not match the pollutant targeted for decomposition, the PCO cleaner may create, as a result of the oxidation process of certain VOCs in indoor air, by-products that are indoor air pollutants.

Current evidence suggests that air cleaning may have a useful role when used in conjunction with source control and ventilation with clean outdoor air.

ADDITIONAL FACTORS TO CONSIDER

Several factors other than the ability of air-cleaning devices to reduce airborne pollutant concentrations should be considered when deciding whether to use air cleaners.

Installation

In-duct air-cleaning devices require sufficient access for inspection during use, repair, and maintenance. Electronic air cleaners and UV lamps should have an accessible power supply and an indicator showing when electrical service is off. The installation of UV lamps requires the addition of access holes into the duct, and the holes must be properly sealed to maintain HVAC efficiency. Mechanical air filters should be installed so that the directional arrow printed on the side of the filter points in the direction of airflow within the system. Incorrectly designed or installed filter frames can cause air seepage, which significantly decreases filter effectiveness. High efficiency filters require well sealed frames to prevent leaks. Installing a higher efficiency and HEPA filter would probably require sheet metal modifications to the existing ductwork to permit the installation of the thicker air cleaner. In addition, a more powerful fan often must be installed to overcome the higher pressure drop.

Operations and Maintenance

In some cases, consumers have been left with no useful manufacturer's instructions that recommend replacement of various air-cleaning devices over their lifetime other than the general manufacturer's operating and maintenance procedures to be followed to ensure adequate air cleaner performance. Air cleaners should be selected to match operating conditions, such as degree of air cleanliness needed, type of pollutant to be removed, and allowable pressure drop. A fan that has sufficient capacity (pressure and airflow ratings) to move air through the filter media must also be included.

Filters and sorbents must be replaced, and the plates or charged media of electronic air cleaners must be cleaned. Electronic air cleaner efficiency decreases as the collecting plates become loaded with particles, so the plates must be cleaned, sometimes frequently, as required by the manufacturer. The cleanings should be scheduled to keep the unit operating at peak efficiency. Special attention must be given to cleaning the ionizing wires of electronic air cleaners designed to target certain contaminants.

During cleaning or replacement of air cleaners, an effort should be made to ensure that pollutants are not re-emitted into the air. For example, excessive movement or air drafts should be avoided when filters are removed. Used filters should be placed in plastic bags or other containers for disposal.

To avoid electrical and mechanical hazards, consumers should make sure air-cleaning devices that require an electrical power supply are listed on the Underwriters Laboratories Web site at www.ul.com or with another recognized independent safety testing laboratory.

Cost

Cost may also be a consideration. Major costs include the initial purchase price, maintenance (such as cleaning or replacing filters and parts), and operation (such as electricity).

The most effective air cleaners—those with high airflow rates and efficient particle capture systems—generally are the most costly. Maintenance costs vary depending on the device, and these costs should be considered when choosing a particular unit. Operating cost is as important as purchase cost because air cleaning

is a continuing process. The cost of professional installation of an electronic air filter or a HEPA filter in the HVAC system must also be considered. Consumers should consider obtaining information on purchase and annual operating costs for various products from *Consumer Reports* magazine and other sources.

Inability to Remove Some Odors

Air-cleaning devices designed to remove particles are incapable of controlling gases and some odors. For example, the odor and many of the carcinogenic gas-phase pollutants from tobacco smoke will remain in filtered air. Particles of liquid tobacco smoke trapped by an air filter may give off odorous organic gases.[12]

Possible Effects of Particle Charging

Another factor to consider related to ion generators is the effect of particle charging on deposition in the respiratory tract. Experiments have shown that particle deposition increases with charge, so using ion generators may not reduce the dose of particles to the lungs.[63, 64] The effect of charge on very fine particles results in their higher deposition rate in the lungs compared to that of uncharged particles.

Soiling of Walls and Other Surfaces

Ion generators generally are not designed to remove from the air the charged particles that they generate. These charged particles deposit on and soil room surfaces such as walls and curtains.[63, 64] Consequently, there is no true effective removal of the particles from the space. Deposited particles, especially those larger than approximately 2 µm, may be re-suspended from the surfaces when disturbed by human activities such as walking or vacuuming.

Noise

Noise may also be a consideration in selecting a portable air cleaner that contains a fan. Portable air cleaners that do not have fans typically are much less effective than units that have them. In tests by Consumers Union, the largest portable air cleaners were the noisiest on their most effective high speed settings.[65] However, some performed more quietly at low speed than many smaller cleaners do on high. Some larger portable units operating at low speed were found to be quiet enough for most households.[22]

CONCLUSION

Indoor air pollution is among the top five environmental risks to public health. The best way to address this risk is to control or eliminate the sources of pollutants and to ventilate a home with clean outdoor air. The ventilation method, however, may be limited by weather conditions or undesirable levels of contaminants in outdoor air. If these measures are insufficient, an air-cleaning device may be useful. While air-cleaning devices may help control the levels of airborne particles including those associated with allergens and, in some cases, gaseous pollutants in a home, air cleaning may not decrease adverse health effects from indoor air pollutants.

This document was prepared to provide housing design professionals, public health officials, and indoor air quality professionals with useful information on the available types of air-cleaning devices and their overall effectiveness in reducing air pollutants and associated health impacts. It is important to remember that there is no scientific evidence that shows air-cleaning devices to be consistently and highly effective in reducing adverse health effects from indoor air pollutants.

GLOSSARY

Acute Having a rapid onset and following a short but potentially severe course.

Adsorption The physical process that occurs when liquids, gases, or suspended matter adhere to the surfaces or in the pores of a material.

Air cleaner A device used to remove particulate or gaseous impurities from the air; examples include electrostatic precipitator, ion generator, ultraviolet germicidal irradiation cleaner, photocatalytic oxidation cleaner, and gas-phase air filter.

Air filter A device that removes particulate material from an airstream, also called an "air cleaner."

Airflow resistance See **Pressure drop**.

Allergen A chemical or biological substance (e.g., pollen, animal dander, or house dust mite proteins) that can cause an allergic reaction characterized by hypersensitivity (an exaggerated response).

Allergic respiratory disease Impairment of the normal state of the respiratory system resulting from exposure—usually by inhalation—to an allergen.

Allergy An exaggerated or pathological reaction to breathing, eating, or touching substances that have no comparable effect on the average individual.

Asthma A usually chronic inflammatory disorder of the airways characterized by intermittent episodes of wheezing, coughing, and difficulty breathing, sometimes associated with an allergy to inhaled substances.

Bacterial spore Inactive phase of bacteria, with a thick protective coating that allows the bacteria to survive harsh environmental conditions.

CADR The Clean Air Delivery Rate (CADR) is the measure of portable room air cleaner performance. This is defined as the measure of the delivery of contaminant-free air by a portable household electric room air cleaner, expressed in cubic feet per minute (cfm). CADRs are always the measurement of a unit's performance as a complete system.

Chemisorption A process whereby a chemical substance adheres to a surface through the formation of a chemical bond.

Chronic Marked by long duration, by frequent recurrence over a long time, and often by slowly progressing seriousness.

Corona discharge An electrical discharge brought on by the ionization of a fluid surrounding a conductor, which occurs when the potential gradient exceeds a certain value.

Dander Minute scales of skin. Dander also may contain hair or feathers.

Disinfection The process of any reduction or prevention of growth in a microbial population with no percentage efficiency specified.

Double-blind study A type of clinical trial study design in which the study participants and the investigators do not know the identity of the individuals in the intervention and control groups until data collection has been completed.

HEPA filter	High-efficiency particulate air filter. Extended surface mechanical air filter having a minimum particle removal efficiency of 99.97 percent for all particles of 0.3 µm diameter, with high efficiency for both larger and smaller particles.
HVAC	Heating, ventilating, and air conditioning.
IAQ	Indoor air quality.
MERV	Minimum efficiency reporting value.
Mold spore	Tiny reproductive structures produced by vegetative mold.
Ozone	An unstable, poisonous allotrope of oxygen that is formed naturally in the ozone layer from atmospheric oxygen by electric discharge or exposure to ultraviolet radiation, also produced in the lower atmosphere by the photochemical reaction of certain pollutants.
Particulate	A small discrete mass of solid or liquid matter that remains individually dispersed in gas or liquid emissions (usually considered to be an atmospheric pollutant).
PCO	Photocatalytic oxidation.
Placebo effect	A usually, but not necessarily, beneficial effect attributable to an expectation that a treatment will have an effect; an effect that is due to the power of suggestion; a sense of benefit felt by a patient that arises solely from the knowledge that treatment has been given.
Pressure drop	The loss of force applied over a filtering media surface due to resistance to airflow.
Rhinitis	Inflammation of the mucous membrane lining of the nose.
Sorption	The common term used for adsorption.
ULPA	Ultra low penetration air filter. Extended surface mechanical air filter having a minimum particle removal efficiency of 99.999 percent for all particles of 0.3 µm diameter, with high efficiency for both larger and smaller particles.
UV	Ultraviolet.
UVGI	Ultraviolet germicidal irradiation.
VOCs	Volatile organic compounds; chemicals that contain carbon and are vaporous at room temperature and pressure.
Vegetative bacteria and molds	Microorganisms that are in the growth and reproductive phase, i.e., not spores.

REFERENCES

1. *Consumer's Guide to Radon Reduction.* U.S. Environmental Protection Agency. EPA 402-K-06-094. Revised December 2006.

2. *The Inside Story: A Guide to Indoor Air Quality.* U.S. Environmental Protection Agency. EPA 402-K-93-007. April 1995.

3. *Chapter 25. Air-To-Air Energy Recovery.* Heating, Ventilating, and Air-Conditioning: Systems and Equipment: 2008 ASHRAE Handbook. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. 2008.

4. *Chapter 36. Owning and Operating Costs.* Heating, Ventilating, and Air-Conditioning: HVAC Applications: 2007 ASHRAE Handbook. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. 2007.

5. *Evaluation of Residential Furnace Filters.* Bowser Technical Inc. for Canada Mortgage and Housing Corporation. 1999.

6. *Chapter 28. Air Cleaners for Particulate Contaminants.* Heating, Ventilating, and Air-Conditioning: Systems and Equipment: 2008 ASHRAE Handbook. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. 2008.

7. *NAFA Guide to Air Filtration.* National Air Filtration Association. 4th Edition. 2007.

8. Ozone Generators that are sold as air cleaners: An assessment of effectiveness and health consequences. U.S. Environmental Protection Agency. http://www.epa.gov/iaq/pubs/ozonegen.html

9. Shaughnessy, R.J., and Sextro, R.G. 2006. What Is an Effective Portable Air-Cleaning Device? A Review. *Journal of Occupational and Environmental Hygiene.* Vol. 3, pp. 169-181.

10. Weshler, C. J. 2006. Ozone's Impact on Public Health: Contributions from Indoor Exposures to Ozone and Products of Ozone-Initiated Chemistry. *Environmental Health Perspectives.* Vol. 114, No 10, pp. 1489-1496.

11. Fugler, D., Browser, D., and Kwan, W. 2000. The effects of improved residential furnace filtration on airborne particles. *ASHRAE Transactions 2000.* pp. 317-326.

12. Offermann, F. J., Loisell, S.A., and Sextro, R.G. 1992. Performance of air cleaners in a residential forced air system. ASHRAE Journal. July 1992. Pp. 51-57.

13. *Gravimetric and dust-spot procedures for method of testing air-cleaning devices used in general ventilation for removing particulate matter.* ANSI/ASHRAE Standard 52.1-1992. American Society of Heating, Refrigerating and Air-Conditioning Engineers Inc. 1992.

14. *HEPA and ULPA Filters.* Recommended Practices and Standards IEST-RP CC001.4. Institute of Environmental Sciences and Technology. Mt. Prospect, Illinois. 1993.

15. *Method of testing general ventilation air-cleaning devices for removal efficiency by particle size.* ANSI/ASHRAE Standard 52.2-2007. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. 2007.

16. *Ventilation and acceptable indoor air quality in low-rise residential buildings.* ANSI/ASHRAE Standard 62.2.-2007. American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. 2007.

17. Fisk, W.J., Faulkner, D., Palonen, J., and Seppanen, O. Particle air filtration in HVAC supply air streams: performance and cost implications of various methods of reducing indoor concentrations of particles. *HPAC Engineering, Heating/Piping/Air Conditioning. July 2003.*

18. *Method for Measuring Performance of Portable Household Electric Room Air Cleaners.* Standard ANSI/AHAM AC-1-2006. Association of Home Appliance Manufacturers (AHAM). 2006.

19. Directory of Certified Room Air Cleaners. Edition No.1 – January 2008. Association of Home Appliance Manufacturers (AHAM). http://www.aham.org. On line searchable directory http://www.cadr.org/consumer/certified.html. Toll-free phone number 800-267-3138. 2004.

20. Bascom, R., Fitzgerald, T. K., Kesavanathan, J., and Swift, D. L. 1996. A portable air cleaner partially reduces the upper respiratory response to sidestream tobacco smoke. *Appl. Occup. Environ. Hyg.* Vol.11, No. 6, pp. 553-559.

21. Battistoni, P., and Fava, G. 1993. Electrostatic air cleaner in the control of tobacco smoke. *Intern. J. Environmental Studies* Vol. 44 pp. 299-305.

22. Air Cleaners: Behind the hype. *Consumer Reports.* Vol. 68, No. 10, pp. 26-29. October, 2003.

23. Custovic, A., Simpson, A., Pahdi, H., Green, R.M., Chapman, M.D., and Woodcock, A. 1998. Distribution, aerodynamic characteristics, and removal of the major cat allergen Fed d I in British homes. *Thorax, British Medical Association,* Vol. 53, pp. 33-38.

24. De Blay, F., Chapman, M.D., and Platts-Mills, A.E. 1991. Airborne Cat Allergen (Fel d I): Environmental control with the cat in situ. *American Review of Respiratory Disease,* Vol.143, pp. 1334-1339.

25. Green, R., Simpson, A., Custovic, A., Faragher, B., Chapman, M., and Woodcock, A. 1999. The effect of air filtration on airborne dog allergen. *Allergy.* Vol. 54, pp. 484-488.

26. *Clearing the Air: Asthma and Indoor Air Exposures.* Committee on the Assessment of Asthma and Indoor Air, Division of Health Promotion and Disease Prevention, Institute of Medicine. 2000.

27. Van der Heide, S., Aalderen, W. M.C., Kauffman, H.F., Dubois, A.E.J., and de Monchy, J.G.R. 1999. Clinical effects of air cleaners in homes of asthmatic children sensitized to pet allergens. *Journal of Allergy and Clinical Immunology.* Vol. 104, No. 2, pp. 447-451.

28. Wood, R. A., Johnson, E.F., Van Natta, M.L., Chen, P.H., and Eggleston, P.A. 1998. A placebo-controlled trial of a HEPA air cleaner in the treatment of cat allergy. *American Journal of Respiratory and Critical Care Medicine* Vol. 158, pp. 115-120.

29. New Concerns about Ionizing Air Cleaners. *Consumer Reports.* Pp. 22-25. 2005.

30. *Field test methods to measure contaminant removal effectiveness of gas-phase air filtration equipment – phase II, 791-RP (1098-TRP).* SPC 145. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. 2004.

31. Miller, J.F., Rodberg, J.A., and Keller, G.H. 1991. Benzene adsorption onto activated carbon and benzene destruction by potassium permanganate-loaded alumina. *Union Carbide Chemicals and Plastics Company.* South Charleston, WV.

32. Ramanathan, K., Debler, V.L., Kosusko, M., Sparks, L.E. 1988. Evaluation of control strategies for volatile organic compounds in indoor air. *Environmental Progress.* Vol. 7, No. 4, pp. 230-235.

33. *Guidelines for environmental infection control in health care facilities.* U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. 2003.

34. Kowalski, W.J. and Bahnfleth, W. 1998. Airborne respiratory diseases and mechanical systems for control of microbes. *Heating/Piping/Air Conditioning.* Vol. 70, No. 7, pp. 34-48.

35. Kemp, S.J., Kuehn, T.H., and Pui, D.Y.H. 1995. Filter Collection efficiency and growth of microorganisms on filters loaded with outdoor air. *ASHRAE Transaction 3853 (RP-625).* Pp. 228-237.

36. Scheir, R., and Fencl, F. 1996. Using UVC technology to enhance IAQ. *Heating/Piping/Air Conditioning.* Vol, 68.

37. Jankowska, E., Reponen, T., Willeke, K., Grinshpun, S.A., and Choi, K. J. 2000. Collection of fungal spores on air filters and spore reentrainment from filters into air. J. *Aerosol. Sci.* Vol. 31, No.8, pp. 969-978.

38. *VanOsdell, D., and Foarde, K. 2002. Defining the effectiveness of UV lamps installed in circulating air ductwork.* Prepared for the Air-Conditioning and Refrigeration Technology Institute, RTI International. ARTI-21CR/610-40030-01.

39. Kowalski, W.J. and Bahnfleth, W. 2000. UVGI design basics for air and surface disinfection. *Heating/Piping/Air Conditioning.* Vol. 72, No. 1, pp. 100-110.

40. Levetin, E., Shaughenessy, R., Rogers, C., and Scheir, R. 2001. Effectiveness of germicidal UV radiation for reducing fungal contamination within air-handling units. *Applied and Environmental Microbiology.* Vol. 67, No. 8, pp. 3712-3715.

41. Cundith, C.J., Kerth, C.R., Jones, W.R., McCaskey, T.A., and Kuhlers, D.L. 2002. Microbial reduction efficiencies of filtration, electrostatic polarization, and UV components of a germicidal air-cleaning system. *Journal of Food Science.* Vol. 67, No.6, pp. 2278-2281.

42. Xu, P., Peccia, J., Fabian, P., Martyny, J.W., Fennelly, K.P., Hernandez, M., and Miller, S.L. 2002. Efficacy of ultraviolet germicidal irradiation of upper room air in inactivating airborne bacterial spores and mycobacteria in full scale studies. *Atmospheric Environment.* Vol. 37, pp. 405-419.

43. Menzies, D., Pasztor, J., Rand, T., and Bourbeau, J. 1999. Germicidal ultraviolet irradiation in air-conditioning systems: effect on office worker health and wellbeing: A pilot study. *Occupational and Environmental Medicine.* Vol. 56, pp. 397-402.

44. Menzies, D., Popa, J., Hanley, J.A., Rand, T., and Milton, D.K. 2003. Effect of ultraviolet germicidal lights installed in office ventilation systems on workers' health and wellbeing: double-blind multiple crossover trial. *The Lancet.* Vol. 362, pp. 1785-1791.

45. *Mold Remediation in Schools and Commercial Buildings.* U.S. Environmental Protection Agency. EPA 402-K-01-001. March 2001.

46. *Germicidal lamps and applications.* Phillips Lighting Division. 1985.

47. *Disinfection by UV – radiation.* Phillips Lighting Division. 1992.

48. Henschel, B. 1998. Cost analysis of activated carbon versus photocatalytic oxidation for removing organic compounds from indoor air. *J. Air & Waste Management Association.* Vol.48, No. 10, pp. 985-994.

49. Tompkins, D.T., Lawnicki, B.J., Zeltner, W.A., and Anderson, M.A. 2003. Evaluation of photocatalysis for gas-phase air cleaning - Part 1: Process, Technical and Sizing Considerations. *ASHRAE Research Project 1134-RP.* Conducted: December 1999 – November 2002, University of Wisconsin.

50. Tompkins, D.T., Lawnicki, B.J., Zeltner, W.A., and Anderson, M.A. 2003. Evaluation of photocatalysis for gas-phase air cleaning - Part 2: Economics and Utilization. *ASHRAE Research Project 1134-RP.* Conducted: December 1999 – November 2002, University of Wisconsin.

51. Chen, W., Zhang, J., and Zhang, Z. 2005. Performance of air cleaners for removing multiple volatile organic compounds in indoor air. *ASHRAE Transactions 111 (2005),* pp. 1101-1114.

52. Turchi, C.S., Rabago, R., Jassal, A. 1995. Destruction of volatile organic compound (VOC) emissions by photocatalytic oxidation (PCO): Bench scale test results and cost analysis. *Sematech.* Technology Transfer # 95082935A-ENG.

53. Zorn, M.E., Tompkins, D.T., Zeltner, W.A., and Anderson, M.A. 1999. Photocatalytic oxidation of acetone vapor on TiO2/ZrO2 thin films. *Applied Catalysis B: Environmental.* Vol. 23, pp. 1-8.

54. Zorn, M.E. 2003. Photocatalytic oxidation of gas-phase compounds in confined areas: investigation of multiple components systems. *Proceedings of the 13th Annual Wisconsin Space Conference.* August 14-15, 2003.

55. Jardim, W. F., and Alberci, R.M. 1997. Photocatalytic destruction of VOC in the gas-phase using titanium dioxide. *Applied Catalysis B: Environmental.* Vol. 14. No 1, pp. 55-68.

56. Blake, D.M., Jacoby, W.A., and Nimlos, M. 1992. Identification of by-products and intermediates in the photocatalytic oxidation of gas-phase trichloroethylene. *Proceedings. 6th International Symposium on Solar Thermal Concentrating Technologies,* September 28 – October 2, 1992, Vol. 2.

57. Alberci, R.M., Mendes, M.A., Jardin, W.F., and Eberlin, M.N. 1998. Mass spectrometry on-line monitoring and MS2 product characterization of TiO2/UV photocatalytic degradation of chlorinated volatile organic compounds. *Journal of the American Society for Mass Spectrometry.* Vol. 9. No 12, pp. 1321-1327.

58. Reisman, R.E., Mauriello, P.M., Davis, G.B., Georgitis, J.W., and DeMasi, J. 1990. A double-blind study of the effectiveness of a high-efficiency particulate air (HEPA) filter in the treatment of patients with perennial allergic rhinitis and asthma. J. *Allergy Clin. Immunol.* Vol. 85, No. 6, pp. 1050-1057.

59. Morgan, W.J., Crain, E.F., Gruchalla, R.S., O'Connor, G.T., Kattan, M. 2004. Results of Home-Based Environmental Intervention among Urban Children with Asthma. *The New England Journal of Medicine, 352,* pp. 1068-1080.

60. Wood, R. 2002. Air-filtration devices in the control of indoor allergens. *Current Allergy and Asthma Reports.* Vol. 2, pp. 397-400.

61. Luczynska, C.M., Li, Y., Chapman, D., and Platts-Mills, T.A.E. 1988. Airborne concentrations and particle size distribution of allergen derived from domestic cats (Felis domesticus): Measurements using cascade impactor, liquid impinger and a two site monoclonal antibody assay for Fel d I. Presented to the *American Academy of Allergy Meeting in Los Angeles.* March 4, 1988.

62. Dorsey, J. and Davidson, J.H. 1994. Ozone production in electrostatic air cleaners with contaminated electrodes. *IEEE Transactions on Industry Applications,* Vol. 30, *No. 2,* pp. 370-376.

63. Offermann, F.J., Sextro, R.G., Fisk, W.J., Grimsrud, D.T., Nazaroff, W.W., Nero, A.V., Revzan K.L., and Yater J. 1985. Control of respirable particles in indoor air with portable air cleaners. *Atmospheric Environment.* Vol. 19, No. 11, pp. 1761-1771.

64. Melandari, C., Tarrani, G., Prodi, V., De Zaiacomo, T., Formignani, M., and Lombardi, C.C. 1983. Deposition of charged particles in the human airways. *J. Aerosol Sci.,* Vol. 14, pp. 184-186.

65. Clearing the air: A guide to reducing indoor pollution. *Consumer Reports.* p. 41-49. February, 2002.

ADDITIONAL INFORMATION

Visit our Web site for any additional information about indoor air quality at http://www.epa.gov/iaq.

An electronic copy of this document Residential Air Cleaners (Second Edition) A Summary of Available Information, EPA 402-F-09-002, August 2009, is available at http://www.epa.gov/iaq/pubs/residair.html

An electronic copy of the EPA brochure Guide to Air Cleaners in the Home, EPA 402-F-08-004, May 2008, addressed to the general public is available at http://www.epa.gov/iaq/pdfs/aircleaners.pdf

For hard copies of Guide to Air Cleaners in the Home and other EPA indoor air publications, contact:

National Service Center for Environmental Publications (NSCEP)
P.O. Box 42419
Cincinnati, OH 42419
phone: (800) 490-9198
fax: (301) 604-3408
Web site: http://www.epa.gov/nscep

ADDITIONAL RESOURCES

Residential Air-Cleaning Devices – Types, Effectiveness and Health Impact. American Lung Association.
Web site: http://www.lungusa.org

Air-Cleaning Devices for the Home, Frequently Asked Questions. California Air Resources Board and the California Environmental Protection Agency.
Web site: http://www.arb.ca.gov/research/indoor/acdsumm.pdf

Survey of the Use of Ozone-generating Air Cleaners by the California Public. California Air Resources Board and the California Environmental Protection Agency, January 2007.
Web site: http://www.arb.ca.gov/research/apr/past/05-301.pdf

Hodgson, A.T., Hugo Destaillats, H., Hotchi, T., Fisk, W.J. 2007. Evaluation of a Combined Ultraviolet Photocatalytic Oxidation (UVPCO)/Chemisorbent Air Cleaner for Indoor Air Applications. *Lawrence Berkeley National Laboratory.* Paper LBNL-62202.

Hodgson, A.T., Sullivan, D.P., Fisk, W.F. September 30, 2005. Evaluation of Ultra-Violet Photocatalytic Oxidation (UVPCO) for Indoor Air Applications: Conversion of Volatile Organic Compounds at Low Part-per-Billion Concentrations. *Lawrence Berkeley National Laboratory.* Paper LBNL-58936.

EXHIBIT 22

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

\- - - - - - - - - - - - - - - - - -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

\- - - - - - - - - - - - - - - - - -

DEPOSITION OF DAVID A. WESTLIN

VOLUME I, PAGES 1 - 189

DECEMBER 16, 2016

(The following is the deposition of DAVID A. WESTLIN, taken pursuant to Notice of Taking Deposition, via videotape, at the offices of Ciresi Conlin L.L.P., 225 South 6th Street, Suite 4600, Minneapolis, Minnesota, commencing at approximately 10:02 o'clock a.m., December 16, 2016.)

MS. GARCIA: Object to the form about --
Q. And the last --
MS. GARCIA: -- the word "you." It didn't go directly to Mr. Westlin.
Q. Mr. Westlin, you received a copy of this report; didn't you?
A. Yes.
Q. It would be very odd if you didn't; right?
MR. SMITH: Object to form.
A. Yes, that's correct.
Q. Okay. And when you received this, you got a letter letting you know that this was the final inspection report just for your files, right, and this is something you were provided a copy of.
A. That's correct.
Q. Okay. Now also in the final paragraph of this letter it states that there were some what's called FDA 483 inspectional observations that were provided to the company; correct?
A. That's correct.
Q. And that the company actually issued a response to those; correct?
A. Yes.
Q. I want to talk a little bit about some of the things that the FDA observed, and I'd like you to

flip with me to page four of this inspection report.
A. Okay.
Q. In the first paragraph under "Inspectional Coverage" -- I'm sorry.
There's a section entitled "Inspectional Coverage;" correct?
A. Yes.
Q. Okay. In the second paragraph it talks about that the inspection had a discussion about contamination concerns. Do you remember having those discussions?
A. Yes.
Q. Okay. In fact, you personally had discussions with FDA personnel; correct?
A. That's correct.
Q. Okay. And during those discussions, if you'll notice into the third sentence of this paragraph, the FDA inspector states that "The warming unit has a .2 micron HEPA filter which is in place as a secondary safeguard against contamination after the hospital/medical clinic's air filtration system." Do you see that sentence?
A. I do.
Q. That is not an accurate sentence; is it?
A. No, it is not.

MR. SMITH: Object to form.
Q. When you saw this sentence, you knew it was not accurate; correct?
MR. SMITH: Object to the form.
A. I can't remember that I noticed it. If I had, I probably would have said something. But no, I don't remember noticing that HEPA was described here.
Q. Okay. And in fact the company did nothing to correct this piece of information; right?
A. That's correct.
Q. Okay. When you're provided the inspectional observations from the FDA facility, that's something that you would have reviewed; correct?
A. The 483 notice?
Q. Sure.
A. Yes.
Q. Okay. So in reviewing and responding to the 483 notice, that's an important part of your job.
A. Correct.
Q. There's nothing frivolous about that.
A. Correct.
Q. It's important to do a thorough job and give the government accurate information.
A. That's correct.
Q. And that did not happen in this case.

MS. GARCIA: Object to the form.
And I want to go back several questions. You had a predicate to your question "during the discussions" and then you asked him do you see this sentence. I object to the predicate to that question.
Q. All right. So that didn't happen in this case.
A. What didn't happen?
MR. SMITH: Object to the form.
Q. And now we're -- yeah, let's go back. Let's try it again. Scroll back for me. Let's -- let's try it again this way.
In reviewing and responding to the 483 notice, that's a non-frivolous function of your job.
A. That's correct.
Q. Okay. It's important that that's done thoroughly and accurately.
A. That's correct.
Q. That did not happen in this case.
MS. GARCIA: Objection to form.
MR. SMITH: Object to the form.
A. I don't know that it didn't happen. I presume it was done correctly.
Q. Okay. Well if the 483 had been responded to correctly, there is no way that the inspectional

EXHIBIT 23

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

- - - - - - - - - - - - - - - - - -

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:
All Actions MDL No. 15-2666 (JNE/FLM)

- - - - - - - - - - - - - - - - - -

DEPOSITION OF GARY R. MAHARAJ
VOLUME I, PAGES 1 - 307
JANUARY 18, 2017

(The following is the deposition of GARY R. MAHARAJ, taken pursuant to Notice of Taking Deposition, via videotape, at the offices of Ciresi Conlin L.L.P., 225 South 6th Street, Suite 4600, Minneapolis, Minnesota, commencing at approximately 9:27 o'clock a.m., January 18, 2017.)

Page 94

universally, or electronics that could plug into any -- any plug in the world.
Q. Well didn't you already have that?
A. Yes, in the 505, but I believe the components to accommodate that were different models.
Q. So the functionality of being able to be used worldwide that was present in the 505, salespeople wanted it in the 750 also.
A. No, I --
The 505 for United States would have different components than the 505 for Europe.
Q. I understand that.
A. Yeah. And they wanted the 750 to have less variability.
Q. Less variability?
A. In the components. That it would be a universal blower that can blow, you know, a blanket anywhere.
Q. So the salespeople wanted a universal functionality that could be used anywhere in the world from an electronic standpoint.
A. That would -- that would be an advantage, yes.
Q. Okay. Anything else you recall?
A. I can't.

Page 95

Q. Now did you know, at the time you undertook your responsibilities as the champion of the 750, that airborne particles posed an avoidable infection risk?
A. Airborne particles in the operating room?
Q. Yes.
A. We knew that airborne particles -- or that infections could be related to the -- from the surgical staff and the number of people in the room and the movement of people in the room.
Q. Yes. And did you know that, at the time you undertook your responsibility as champion of the 750, that that was an avoidable risk that could be avoided through design and other precautions that could be taken?
A. I -- I don't --
Avoidable by -- by --
Q. By the design --
A. -- the operating room --
Q. -- you may have, by operating room procedures, et cetera.
A. No. We --
One, contamination was not a risk we believed was a con -- an issue with the Bair Hugger design since it had been, we thought, fairly thoroughly studied before, and in fact that the -- the

Page 96

major issue was getting to pre -- to reduce infections was getting as much warmth as possible to that patient as quickly as you can. So --
Q. What --
A. Yeah.
Q. -- studies or tests did you rely on in saying that airborne particles were not a problem for the Bair Hugger at the time you undertook responsibility as champion of the 750?
A. It was -- it was the studies that had been conducted --
Q. No.
A. -- before I was -- I got onto the Bair Hugger. There had been studies. I don't recall the names of the studies, but Scott Augustine, who was also on the 750 team, had -- had them studied or they'd been studied by independent researchers.
Q. What tests did Augustine ever conduct that addressed that issue?
If there are none, tell me there are none.
MR. GOSS: Object to form.
A. Well --
MR. BREWER: Pardon me. It's been asked and answered I also think.
A. I don't know. I know Scott had conducted

Page 97

one, potentially with Paul Iaizzo, but I don't know the names of the others.
Q. What studies did Dr. Augustine conduct or test at Augustine that addressed that specific issue?
A. At Augustine, I don't know.
Q. Okay. Did you ever find any test at Augustine which addressed that issue?
A. Can you repeat the issue?
Q. Whether airborne particles -- strike that.
The issue is your assertion that airborne particles were not a problem with regard to the Bair Hugger. What tests are you aware of, if any, conducted at Augustine to address that specific issue?
A. I don't recall, and I'm not aware of some at that time.
(Discussion off the stenographic record.)
Q. Now I want to direct your attention now to the involvement you had in the 750. All right, sir?
A. Okay.
Q. Because, obviously, you were not involved at all in the 505 design.
A. No.
Q. Okay. And first, let's deal with the filter. All right? Do you know what filter was on the 750?

conduct our business in a safe, re -- responsible manner, and obeying all the laws of the nations where we conduct business, yes.
Q. You were the ultimate person responsible; correct?
A. I am the CEO, yes.
Q. The buck stops at your desk; correct?
A. I don't know what that means, "the buck stops."
Q. You don't.
A. No.
Q. Okay.
A. The dollar?
Q. Yeah.
A. Okay. I --
Q. You never heard that phrase.
A. Well I know it means something about responsibility, but I -- there are no dollars stopping at my desk.
Q. Okay.
A. Sorry.
Q. You mean literally dollars don't fly in and stop at your desk.
A. No.
Q. Is that what you mean?

A. No, no.
Q. Is that what you mean?
A. I -- I mean --
Q. Did you think that's what I was asking?
A. I think you were using an analogy of the responsibility, yeah.
Q. You don't think I was asking if dollars come flying into your room and stop at your desk.
A. No, no, no. No, no. But --
Q. Now you were the one who provided the history of the contamination issues that the company was facing in 2010; correct?
MR. GOSS: Object to form.
A. When the -- the inspector came in we -- it was one of the -- I believe they were looking at three or four items, so I --
Q. I didn't ask you that.
A. Yes, I chatted with her about the -- the contamination debate that was on -- ongoing in -- with our competitors, like Dr. Augustine. So yes, I did talk to her about that.
Q. Is your answer yes?
A. Yes to --
Q. You were the person who gave the brief history of the contamination issue.

A. Yes. I would have chatted with her.
Q. Thank you.
A. Yes.
Q. And one of the pieces of information that was provided was that the unit has a two-micron HEPA filter which is in place as a secondary safeguard against contamination after the hospital/medical clinic's air filtration systems; correct?
MR. GOSS: Object to form, foundation.
A. No, I -- I never would have said that.
Q. Okay. If you could go to "Inspectional Coverage," --
A. Uh-huh.
Q. -- page 8057, second paragraph, third sentence. Are you there, sir?
A. Yeah.
Q. Quote, "The warming unit has a 0.2 micron HEPA filter which is in place as a secondary safeguard against contamination after the hospital/medical clinic's air filtration systems." Do you see that?
A. Yes.
Q. Okay. That's what was told to the FDA; correct?
MR. GOSS: Object to form, foundation.
A. No, clearly not. That's what this

inspection report says from the FDA.
Q. From the FDA.
A. Yes.
Q. Well did --
You read it when you received it.
A. This report was received, I don't know, maybe almost nine months after or 12 months after the --
When was it received?
Q. The inspection ended on January 6th.
A. 2010, yeah.
Q. Correct.
A. I'm trying to go figure out when this was received. This may have been nine months after.
Q. Did you read it was my question.
A. I can't recall. I -- I may have, yes.
Q. It's an important document; isn't it?
A. It's a -- it's a closeout report provided to the company.
Q. That's an important document.
A. Yes. I mean it is -- it is a -- it is a summary of the FDA's viewpoint.
Q. Did you direct anyone to correct that statement?
A. I don't recall the HEPA statement, because

interrupt me and the witness, that's what we're going to do.
MR. CIRESI: You have your choice.
MR. BREWER: We'll seek protection, that's what we'll do.
MR. CIRESI: You can do whatever you want.
MR. BREWER: Well let's try and act, like you said you would at the beginning of the deposition, with a little courtesy and -- and professionalism and we'll be fine.
MR. CIRESI: Well we'll expect that from you.
MR. BREWER: Good.
MR. CIRESI: Now I'm again going to ask the question.
THE WITNESS: Uh-huh.
Q. What testing was done by Arizant to determine whether the Bair Hugger contributed to infections? By Arizant.
A. There was no -- not any evidence that we were aware of that the Bair Hugger contributed to any infections, --
Q. Excuse me, --
A. -- and so --
Q. -- sir --

A. -- so there was --
Well I'm answering your question. And in fact, the Bair Hugger significantly reduced the level of infections. We had no patient reports. So no -- at that point -- internal testing had been conducted. It had been well vetted in the clinical field by independent researchers.
MR. CIRESI: Move to strike, non-responsive.
Q. What testing was done internally by Arizant before it put the Bair Hugger on the market that went to the issue of whether it would contribute to infections --
MR. BREWER: Two objections --
Q. -- at the surgical site?
MR. BREWER: Two objections -- pardon me.
Q. If it was none, just tell me none.
MR. BREWER: Two objections: asked and answered, and I think it lacks proper foundation.
Go ahead.
MR. CIRESI: You may answer.
A. Yeah. So I'll repeat my answer.
Q. No, I'm not asking you to repeat your answer.
A. Right. There was --
Q. I want to know -- excuse me, sir.

A. Yeah.
Q. What tests were done internally addressed to the issue of whether the Bair Hugger contributed to infections --
A. There were --
Q. -- at any time --
A. Right.
Q. -- before it went on the market or when you were there?
A. The --
MR. BREWER: The same objections.
A. Yes. I -- I recall one test of whether it disrupted laminar-flow patterns, which would be imputed to change of performance of those devices. I believe it occurred in -- with an independent lab in Germany. I can't remember when it was done.
Q. Are you talking about the Sessler/Olmstead study?
A. I -- I don't know that study precisely, but I remember there was a German -- forget the name of the company. They assess laminar flow and qualify them, and it was a --
Q. Was it -- was it in the Netherlands?
A. The Netherlands, yes. Sorry. It was --
Q. Conducted --

A. It was a German team.
Q. Conducted at two hospitals?
A. I can't remember how many hospitals. And --
Q. Do you know what the results of that study were?
A. I believe so. It was --
I was actually present at one of them, and it was demonstrated that the airflow pattern that would -- that laminar flow -- it didn't disrupt the laminar flow airflow patterns in any clinically significant manner -- or significant manner when it came to particulates.
Q. And by "clinically significant," you're talking about statistical significance?
MR. GOSS: Object to form.
A. I don't know if it --
Q. Just tell me if you know.
A. I don't -- no, I didn't --
I have not seen that paper, I left before that was published, but I don't know what the clinical -- or the statistical significance was.
Q. So you don't know what the results of the study were --
A. Well I --
Q. -- specifically.